CONSUMER PROTECTION ISSUES INVOLVING IN VITRO FERTILIZATION CLINICS

HEARING

BEFORE THE

SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES, AND ENERGY

OF THE

COMMITTEE ON SMALL BUSINESS
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

WASHINGTON, DC, MARCH 9, 1989

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CONSUMER PROTECTION ISSUES INVOLVING IN VITRO FERTILIZATION CLINICS

THURSDAY, MARCH 9, 1989.

House of Representatives,
Subcommittee on Regulation, Business
Opportunities and Energy,
Committee on Small Business,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:12 a.m., in room 2359-A, Rayburn House Office Building, Hon. Ron Wyden (chairman of the subcommittee) presiding.

Chairman Wyden. The Subcommittee on Regulation will come to order. Today, the subcommittee holds its second hearing on in vitro fertilization in the clinics that promote and perform this important treatment.

IVF, the process by which a woman is artificially impregnated with her own fertilized egg, is part of an enormous growth industry. One American couple in five is now considered infertile, and that includes an estimated 35,000 married couples in my home State of Oregon. Couples with these problems spend an estimated $1 billion per year on infertility treatments with $30 million to $40 million spent specifically on IVF procedures.

Now, at the subcommittee's first hearing we were repeatedly told by witnesses that infertile couples find it extremely difficult to obtain clear, understandable, and unbiased information about the performance of these clinics. Many of these couples are desperate to have children. Some have been on an emotional rollercoaster for years attempting to conceive through a variety of procedures. They are vulnerable to exploitation and to those who would unfairly try to rip them off.

American families are entitled to the facts. They ought to be protected from the hype about the fertility business.

In an effort to supply facts to American families and consumers the subcommittee has surveyed 224 clinics across the country doing IVF treatments. These clinics were asked to respond to 28 questions regarding their services and their success rates. Today we are releasing these results and the Chair would like to make just a few brief observations as we do.

First, this survey was developed with the help of the American Fertility Society leadership and to them we owe our special appreciation. The questionnaire pooled 224 clinics, 191 responded. Of those 165 said that they performed IVF treatment; 25 do not do the procedure. Some 146 clinics provided complete data from 1987 and

1988. Those clinics conducted 26,332 IVF stimulations in that 2-year period resulting in 20,483 egg recoveries at a cost of $4,000 to $7,000 per procedure. These recoveries produce 2,463 live births. That constitutes a success rate of about 9 percent.

[The results of the survey referred to above may be found in the appendix.]

Second, it is quite clear that patient loads are up and demand is increasing rapidly. The clinics treated 8,167 patients in 1987. In 1988 that figure rose to 10,105.

Third, the medical procedures involved are being performed in a variety of settings from giant university medical complexes to single doctor offices. The fact is that physicians and technicians performing these procedures have vastly differing qualifications. Some of the practitioners, according to our survey, have little or no special training in the field.

Fourth, the subcommittee's investigations turned up instances of questionable advertising practices. Success rates are often exaggerated and consumers may be grossly misled.

For example, IVF-Australia, Boston, advised us that its IVF program and I quote: "Only recently began full operation." Yet we have seen clinic ads in the Boston Globe touting the program's 236 live births. To those who know about IVF-Australia it is apparent that the numbers reflect their worldwide experiences—the worldwide experiences for this multiclinic McDonald's of IVF treatment.

But the ad makes no mention of the Boston clinic's lack of track record. There is more than an implication that IVF-Australia, Boston, is producing lots and lots of babies.

The fifth observation that has concerned the subcommittee is that the Federal Trade Commission has turned its back on the problem of misleading IVF advertising. In their regulatory slumber the Federal Trade Commission's policy with respect to IVF has been little more than let the buyer beware. Much more must be done by the Commission which is charged with truth in advertising enforcement to protect couples from slanted or irresponsible advertising.

Sixth, there is virtually no professional or Government oversight of this booming industry. Any practitioner can hold himself or herself out as a fertility specialist. Embryo labs are exempt from even the cursory inspections required at other medical labs. The problem has grown so serious that one of the foremost doctors in the field, Dr. Richard Marrs of the Institute of Reproductive Medicine in Los Angeles, has said that the IVF business will selfdestruct without some form of Government regulation.

In 1987 the Federal Office of Technology Assessment reported that over half of the fertility clinics then operating had failed to produce a live birth.

Today for the first time couples in this country will be able to get clinic-specific information on the majority of IVF practitioner.

But the Chair wishes to urge caution in the use of this data.

Success rates cannot be viewed in a vacuum. Just as they can be abused to give patients false hope of success, they can be misused to give them a falsely dismal view of IVF successes.

For example, clinics who treat the more difficult cases such as male infertility and older women can reflect lower success rates.

But these may be the very clinics some patients need to go to, to treat their specific problems. Others who may carefully select patients most likely to conceive can show very high success rates, but would be of little value to patients whose inherent infertility problems are by nature harder to treat.

This survey is being released so that Americans can make informed choices. We hope that it will serve as a road map to our citizens so that they can ask the right questions and allow them to be able to read between the lines and fill in the blanks left by the clinics themselves. Under the best of circumstances infertile couples face a number of invasive medical procedures, the risk of dangerous complications, and large medical bills.

But it is our view that frustrated couples, some of them in an emotional breaking point, are entitled to a fair shake and the plain facts.

This subcommittee is going to continue its work until such simple basic justice is done. I believe that today's hearing with the expert witnesses that we have asked to join us makes yet another step in the right direction.

I would like first to welcome our first witness, Ms. Jo Beth Williams, is an actress familiar to many of us. She is also the honorary chair of the National Infertility Awareness Week, which is coming up this October.

Ms. Williams, why don't you come forward and we have some very brief formalities that we have to go through. Let's also have you joined at this time by Ann Petter, president of RESOLVE of Boston. Ms. Petter, if you will join us as well.

[Mr. Wyden's statement may be found in the appendix.]

[Instructions to patients and brochures on infertility treatment referred to above follow:]

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June 7, 1989

Dear Patients:

Prompted by complaints that some physicians are exploiting infertile couples throughout the country, the subcommittee over a year ago began its investigation into infertility treatment. We focussed on the new, as yet not terribly successful, but frequently expensive procedures of in vitro fertilization and gamete intrafallopian transfer. The subcommittee has held two hearings to explore these problems specifically to help infertile couples sort through these difficult, crucial issues. We have heard stories from infertile couples pushed to their emotional and financial limits -- stories of their frustrating, freightening and frantic efforts to have a baby. Last year alone, thousands of couples spent between $30 million and $40 million on these treatments.

It is a steep, uphill battle for couples to protect themselves from unscrupulous, unqualified, and self-proclaimed infertility "experts." Concerned practitioners warn that "exploitation is creeping into American gynecology." And while we found that the abuses can take many forms, the complete absence of national, clinic-by-clinic success rates stifled even the most aggressive and inquisitive patients.

"Buyer beware!" That was the message to patients who are deprived of even the most basic consumer protection tools. The Office of Technology Assessment told the subcommittee that couples have great difficulty assessing clinics' performance. The O.T.A. told the subcommittee that, given the absence of standardized reporting mechanisms and advertising that can easily mislead patients, vulnerable couples are often left with exaggerated expectations and that lead to great disappointment.

Our survey of over 200 clinics across the country doing IVF and GIFT is the first of its kind. We hope that it will serve as a roadmap for patients choosing a clinic offering them the best hope of having a baby. And we hope that the American Fertility Society will continue this important effort, with follow-up surveys.

I am particularly pleased to report that it appears these statistics will be available on an ongoing basis. Following the subcommittee's hearings and the release of our IVF/GIFT survey, the American Fertility Society announced that its Society for Assisted Reproductive Technology plans to continue gathering this critical information and making it available to consumers each year. We commend the Society for its efforts and its commitment to infertile patients

It's important, however, not to view these statistics in a vacuum. Simply checking the success rate -- or live baby rate-- does not necessarily give an accurate picture of whether a given clinic can help. Some clinics accept only the more easily treated cases -- therefore causing them to show higher success rates. Other clinics accept the harder to treat cases, with lower rates of success. Yet those may be the very clinics that can best serve different patients' particular needs. Furthermore, newer clinics that have a lower success rate usually will improve as they gain experience.

It's important to remember that this survey is merely a framework to build on. As with much medical treatment, the language is often confusing to lay people. Patients must ask additional questions. And doctors must cut through the jargon and explain programs in clear, understandable terms. The American Fertility Society's pamphlet "Questions to Ask About an IVF/GIFT Program" is a valuable guide in evaluating a clinic.

The survey itself will be most valuable to you if you first read the transcript of our March 9, 1989, hearing. Particularly important are the statements of Dr. Gary Ellis, with the federal government's Office of Technology Assessment that conducted the first national study on infertility, and Dr. Martin Quigley, a representative of the the American Fertility Society's group that specializes in IVF and GIFT treatments. Those statements will help to understand the significance of the statistics -- how the numbers can be inflated to exaggerate chances of taking home a baby and how they can be used to underestimate chances.

Also, the transcript's charts summarize key statistics from each clinic, alphabetically by state, and they should assist in a preliminary review of the data.

Chart I shows stimulation cycles, egg recoveries, embryo transfers, live births and continuing pregnancies -- by year and by procedure.

Chart II indicates the age of the clinic, the number of patients treated, and the numbers of stimulation cycles, egg recoveries, live births and continuing pregnancies for IVF in 1987. The percentages of live births and continuing pregnancies are also shown, based both on success rates per egg recoveries and success rates per stimulation cycle.

Chart III contains the same statistics as Chart II, but for the year 1988.

Chart IV provides the same data as Chart II, for GIFT in 1987.

Chart V gives the GIFT data for 1988.

These charts give a thumbnail sketch of each clinic's performance compared to others in given regions. They do not, in and of themselves, tell either how to rank clinics or how to choose the clinic that would best serve individual patients' needs.

Each clinic's individual response to the subcommittee's survey provides the most valuable information. The questionnaires explain not only the raw statistics, but give a breakdown of the types of infertility that each clinic most typically treats and the age groups treated. Each clinic's response is listed in its entirety at the end of this document -- by state, alphabetically.

The following contacts should be helpful to better understand the information presented in this transcript and the problems of infertility generally.

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Sincerely,

Ron Wyden

RON WYDEN
Chairman

THE AMERICAN FERTILITY SOCIETY

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June 7, 1989

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Dear Patient:

The American Fertility Society, like Congressman Wyden and his subcommittee, believes that informed patients make better decisions about their care. The information published in this survey was collected with the assistance of the American Fertility Society. I hope that this survey will be useful to you as you go about seeking care for your condition.

I would like to add a word of caution about this survey. First, in spite of Congressman Wyden's warning that this information "should not be interpreted in a vacuum", there has been inappropriate use of this information. Some of the media and even some clinics have utilized partial information from the preliminary report to rank clinics. Certain data has been compressed, and charts developed that really are incorrect. It is important that you view the whole picture as you go about choosing a clinic.

The second word of caution is that there were errors in the data collection process that may have led to a clinic reporting a falsely high or seemingly low success rate. All clinics did not interpret the questionnaire in the same way. A question was asked as to how many babies were live born in a given year as a result of the IVF process. The original intent was that births should be reported in reference to the year in which the stimulation cycle was begun. However, some clinics reported the births strictly for the calendar year without any reference to the year of the stimulation cycle. This is particularly obvious in the 1988 data from some clinics where deliveries in that year which could have come from both 1987 and 1988 cycles were reported along with continuing pregnancies, thus leading to an inflated success rate. Any IVF program reporting a success rate greater than 20% should be viewed with caution, as it is likely that the above reporting error accounted for this high percent.

Another inconsistency is that many clinics reported results only for six months in 1988, whereas others reported for the entire year. The questionnaire was sent out in November 1988 to be returned in December 1988. However, Congressman Wyden kept the hearing record open and many clinics did not send in their complete report until well into 1989. Therefore, it is important that you look beyond the simplified charts in this report, and read in detail all the information about a given clinic, and to not focus just on success rates.

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Since in IVF/GIFT it is necessary to recover eggs in order to expect a pregnancy, I believe the most appropriate method to express success is live born deliveries per egg recovery procedure rather than per stimulation cycle. Remember that nationally 25% of all stimulation cycles are cancelled because of recognized low yield situations.

The American Fertility Society is deeply concerned about those few physicians who seem to be exploiting infertile couples, and we hope that the information in this report will help eliminate exploitation and improve patient care.

Sincerely yours,

JBYounger

J. Benjamin Younger, M.D.
President

JBY/kf

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May 31, 1989

Representative Ron Wyden
U.S. House of Representatives
Washington, D.C. 20515

RE: IN VITRO FERTILIZATION SURVEY

Dear Representative Wyden:

Upon receiving your letter of May 22nd, including the March 9th subcommittee hearing information, I immediately reviewed the presentation of the IVF data presented in your survey.

I regret that I, among others, have misinterpreted the questionnaire that you sent out, specifically, question #17 on page three: How many women delivered live infants from IVF/GIFT. I, along with, apparently, many others, put the number of women who delivered in the year 1987, and the number of women who delivered during the year 1988, rather than, the number of women who conceived in 1987 and 1988, but delivered at a later time period. I also made a note by the side of this that the number included some pregnancies that had conceived from the previous year. When this information was then collated on chart 2 and chart 3, your survey did not represent the true delivered live infants plus continuing pregnancies that occurred during the year; for example, in the 1987 IVF data, we actually had 34 women deliver 41 live infants and 2 stillborns from IVF and GIFT which would change the live birth/egg recovery rate in our program to 15%, and the live birth plus continuing pregnancy/egg recovery to 15%, and the live birth plus continuing pregnancy/stimulation cycle to 13%.

In 1988, at the time of the survey, we had 6 live births and 23 continuing pregnancies from 1988 cycles. We also had 24 women deliver in 1988 who conceived in 1987. Therefore, the live births/embryo/egg recovery were 3%, and the continuing pregnancy/egg recovery were 13%, giving a live plus continuing pregnancy/egg recovery of 16% and a live plus continuing pregnancy/cycle start of 13%. This is also consistent with our previous data of 1987. I regret that this misinterpretation occurred; however, if you will refer to question #17 of page 3 of my survey, you will note that I made reference to these numbers.

ART™

I do not think I am alone in misinterpreting your question. In fact, I would say that any program that has an equal or higher number of live births vs. continuing pregnancies in 1988 could be in error, particularly, the following programs: in California the Alta Bates Hospital, the Northridge Hospital, in Colorado the Reproductive Genetics Group, in Connecticut, the Yale School of Medicine Group, in Florida, the Humana Women's Hospital, possibly in Florida, the Sand Lake IVF Center, in Hawaii, the Pacific IVF Institute, in Kansas, the Reproductive Resource Center, in Massachusetts, the Brigham and Women's Hospital, in Michigan, the Blodgett Memorial IVF Center, in New Jersey the Robert Wood Johnson Center, in New York the Columbia Presbyterian, in Ohio the Akron City Hospital and the Cleveland Clinic Foundation, in Tennessee the Vanderbilt Medical Center, in Texas the Center for Reproductive Medicine, in Texas the Trinity IVF and Embryo Transfer Program, in Virginia the Henrico Doctors Hospital and the Medical College of Virginia, and in Washington the Swedish Hospital Medical Center and the University of Washington.

I also noted in the 1987 survey that there were many programs that had continuing pregnancies; for example, in Florida the Northwest Center for Infertility, in Georgia the August Reproductive Biology Group, in Kentucky the Norton Hospital, in North Carolina the North Carolina Memorial Hospital, in New York the Albert Einstein Hospital and the St. Luke's Roosevelt, in Ohio the Akron City Hospital, and in South Carolina the MUSC IVF Program. The request for this information did not reach my office until November 11, 1988. I would think that all requests were sent out at the same time. Again, I feel there was a misinterpretation of the questions, such that, a patient who conceived during 1987 could not, or certainly in my medical judgement, should not be pregnant in November of 1988 (unless someone has extended pregnancy beyond the normal 9 months we usually associate with it !!).

I would strongly encourage a re-survey of groups with a concrete definition of the questions prior to publication of this information for the public. I think it is your goal, as well as mine, that the public obtain accurate information so that they can be informed in making their decisions. I don't feel that this data, as it is currently displayed, provides that. We would be honored to work with you to attempt to rectify this situation. Please feel free to contact me at your convenience. Enclosed is a copy of my survey results and a revision of the information in item #17 on page 3.

I also feel it would be significant to actually present the total number of babies, as many sets of triplets and twins do come to term. In this circumstance, a family is usually complete with one IVF cycle, and the number of babies is as critical as the number of women delivering them. I also feel it would be significant to note any adverse outcomes, such as, premature birth and congenital anomalies, etc. Bad outcomes are certainly worse than no outcome at all.

Again, let me thank you for your commitment to this issue, and let me confirm mine.

Sincerely,

Kathryn L. Honea, M.D.
Medical Director
ART Program

KLH/dd

Enclosures

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SART
1987

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March 20, 1989

The Honorable Ron Wyden
1406 Longworth House Office Building
House of Representatives
Washington, D.C. 20515

Dear Mr. Wyden:

Attached please find a copy of the manuscript I have prepared to go along with my presentation at the VI World Congress of In Vitro Fertilization in Jerusalem on April 3rd, 1989. This chapter will be published in the Proceeding of that meeting by Plenum Press.

An Executive Committee (Officers and Board of Directors) and Membership Committee Meeting of SART was recently held. Several decisions were made which should be of interest. First, beginning with the 1989 data, clinic-specific information will be made available on an annual basis with the permission of the contributing clinic. Clinics who refuse to allow their data to be released will be so identified. Data to be released will be quite comparable to the types of data recently released by your office. We plan to await the birth of all the children resulting from treatment cycles before releasing the data. Thus, the data will be first available for release approximately December 1990. Second, a proposal is being presented to the AFS Board of Directors in July and to the SART membership as a whole in November to require re-application and recertification of SART membership every three years. Included in the recertification requirement would be a specific percentage of live births. At the present time, it is planned that the recertification occur in the second half of 1991. Third, the Committee is currently revising and updating the minimum standard for an IVF program. This will contain specific requirements for the training and experience

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necessary for the personnel involved. These updated standards will be presented to the AFS Board in July and once accepted by the Board, will be published in Fertility and Sterility. Fourth, membership in SART was denied to one clinic that refused to provide verification of the information submitted and membership of a second program was terminated for failure to comply with the bylaw requirements for membership and continuation of membership.

Thus I believe that SART is moving in the right direction to provide a degree of supervision and oversight of the IVF programs.

If I can be of any further service, please don't hesitate to let me know.

Sincerely yours,

Martin M. Quigley, M. D.
President

MMQ:rvm
Enclosure

INFERTILITY

Medical and Social Choices

Box 9-A.—Questions To Ask Before Beginning IVF Treatment

Before beginning IVF treatment at a particular clinic, patients might want to ask a number of questions, including:

- What is the center's pregnancy rate and how is it calculated? Does the clinic measure success by achieving chemically detectable pregnancies, those confirmed by ultrasound, or live births? What is the most meaningful success rate for this particular IVF attempt, based upon the patient's history of responding to stimulation, transfer, and pregnancy? What is the success rate for patients with similar histories?
- Does the clinic implant all fertilized eggs or only those that appear capable of normal development? Does it limit the number of implanted fertilized eggs to minimize risks associated with multiple births? Can the clinic freeze extra embryos for subsequent attempts? What has been the clinic's rate of loss for those embryos?
- Does the clinic offer psychological counseling or have a regular means of referral for those patients who seek help? Is it coordinated with the medical workup and transfer attempts, to anticipate difficulties or disappointments?
- Is the program community-based or a referral center? Referral centers are beginning to train local physicians to handle preliminary workups and ovulation inductions, so that the patients need travel to the main center fewer times.
- Does the clinic offer assistance in obtaining the highest possible insurance reimbursement for the patient? What has been the reimbursement experience of other patients with similar insurance plans? Does the clinic offer a sliding fee scale for patients with low incomes?

SOURCE: Office of Technology Assessment, 1988.

11. Myth: "Infertility is nature's way of controlling population."

Fact:

Zero population growth is an admirable cause in a time of world overpopulation, but it still allows a couple to replace themselves with two children. Individuals or couples can certainly elect the option to be childfree or to raise a single child. Infertility, for those who desire children, is a denial of the right to choose.

12. Myth: "I shouldn't take a month off from the treatment for any reason . . . I just know that this next month will be THE one!"

Fact:

It is very important to establish continuity in your particular treatment for infertility. However, taking some time off from the rigors of infertility treatments can give you a much needed rest and a fresh desire to continue treatment upon returning.

13. Myth: "My doctor knows what's best for me. I'll go along with whatever treatment is suggested without causing any trouble!"

Fact:

Your doctor wants to help you have a baby, and should not object to your asking questions. It is very important to be informed about what treatments are available to you. What is right for one couple may not be right for another, either physically, financially, or emotionally. Educate yourselves through resources like RESOLVE. Don't be afraid to ask questions or to get a second opinion if it makes you feel more confident.

14. Myth: "How will I know when enough is enough and when to stop using the treatment?"

Fact:

You will know when enough is enough. Eventually you will have reduced energy for medical opportunities and treatments. You may begin to think more about parenthood than about pregnancy; you may long for your life to get back to normal.

15. Myth: "I'm not feeling good about anything in my life— my job, hobbies, inability to be a good friend, spouse, or lover." My life will never be the same!"

Fact:

Infertility is a life crisis— it has a rippling effect on all areas of your life. It is normal to feel a sense of failure that can affect your self-esteem and self-image. You WILL move through this crisis. It is a process and may mean letting go of your initial dream. Throughout this process, you can maintain strength if you *stay informed* about the wide range of options and *connect* with others facing similar infertility issues.

Once you have resolved your infertility, your life will seem more in order, you will be on a direct course of action, and you will feel like a "whole" person again!

RESOLVE:
The resource for infertility facts.

RESOLVE, Inc., the only nationwide organization serving the unique needs of people struggling with infertility, provides a comprehensive information network and emotional support services. As a nonprofit, membership organization, RESOLVE serves 15,000 + members in 51 chapters and affiliated groups worldwide.

Through the National Office and local chapters, RESOLVE provides: • the highly acclaimed *National Newsletter* containing medical updates and a forum for sharing experiences; • authoritative Fact Sheets and specialty publications on medical facts, procedures and coping strategies; • counseling through the infertility Hotline; • physician and resource referrals; • registry of adoption services and in vitro clinics; and other specialized services.

For further information and membership, contact the RESOLVE National Office:

5 Water Street
Arlington, MA 02174
(617) 643-2424

Thanks to Barbara Eck Menning, some information in this brochure has been adapted from her book, *Infertility: A Guide for the Childless Couple*, 2nd Edition, Prentice Hall Press, 1988. This book and a wide range of resource materials are available from RESOLVE National Office.

This brochure series on infertility is made possible by a grant from Sandoz Pharmaceuticals Corporation. Sandoz generously supports special projects undertaken by RESOLVE.

SANDOZ BROCHURE SERIES

WHEN YOU'RE WISHING FOR A BABY

MYTHS & FACTS

PRESENTED BY

When trying to have a baby is taking too long, managing your infertility often has a major effect on your daily life. Friends, family and co-workers may try to ease your pain with advice. Well-meaning people will relay stories and their understanding of medical facts, but their advice is often misguided. Their intent is certainly to help you and to provide perspective; however, such comments may actually cause you to feel frustrated and even defensive.

While you proceed with your infertility testing and treatment, strive to separate popular myths from the facts.

1. Myth: "Infertility is a woman's problem."

   Fact:

   This is untrue. It surprises most people to learn that the breakdown of infertility by cause reveals it is a *female* problem in 35% of the cases, a *male* problem in 35% of the cases, a combined problem of the *couple* in 20%, and unknown problems in 10%. It is essential that *both* the man and the woman be tested during an infertility work-up.

2. Myth: "I am the only one who is infertile — everyone else gets pregnant at the drop of a hat."

   Fact:

   You are not alone. One out of every six couples of childbearing age in the United States experiences infertility. Take action to prove to yourself that you are not alone. Join a support group or talk with others who are struggling with infertility so you don't feel so isolated.

3. Myth: "It's all in your head! Why don't you relax or take a vacation . . . then you'll get pregnant!"

   Fact:

   Infertility is not usually due to psychological factors. A physical problem is found in 90% of all infertility cases that have been investigated by a qualified doctor. The stress and emotions an infertile person may exhibit are usually the *result* of infertility, not the cause of it. Improved techniques for diagnosing infertility have made it easier to pinpoint the problem and recommend successful treatment.

4. Myth: "Don't worry so much — it just takes time. You'll get pregnant if you're just patient."

   Fact:

   Infertility is sometimes curable. Between 40% and 50% of those who complete an infertility evaluation will respond to treatment with a successful pregnancy. Some problems respond with higher or lower success rates. Those who do not seek help have a "spontaneous cure rate" of about 5% after a year of infertility.

5. Myth: "If you adopt a baby you'll get pregnant!"

   Fact:

   This is one of the most painful myths for infertile couples to hear. First it suggests that adoption is only a means to an end, not an end in itself. Second, it is simply not true. Studies reveal that the "spontaneous cure rate" for achieving pregnancy is 5% for both those who adopt and those who do not.

6. Myth: "Why don't you just forget it and adopt? After all, there are so many babies out there who need homes!"

   Fact:

   Unfortunately, the traditional adoption options have either changed or diminished, so it may require more time and money than you figured. It is, however, still possible to adopt the healthy baby of your dreams. Although there are many older children and children with special needs available for adoption, these children require parents with special skills.

7. Myth: "Maybe you two are doing something wrong!"

   Fact:

   Infertility is *not* a sexual disorder. It has nothing to do with the ability to perform normally in sexual relations. In the vast majority of cases, infertile men and women are capable of experiencing the same range of sexual responses as other couples.

8. Myth: "Our sex life will never be the same."

   Fact:

   Sex on demand; sex according to ovulation does take its toll on intimacy. Make sure you talk openly about this as a couple. Consider other ways of communicating your love and support — massage, hugging, snuggling can enhance communication and closeness.

9. Myth: "My partner might leave me for a fertile partner."

   Fact:

   In fact, some couples separate as a result of the stress of infertility. The majority of couples do survive the crisis, learning in the process new ways of relating to each other, which will deepen their relationship in years to come.

10. Myth: "Perhaps this is God's way of telling you that you two aren't meant to be parents!"

    Fact:

    It is particularly difficult to hear this when you are struggling with infertility — you know what loving parents you would be, and it is painful to have to explain to others that you have a *MEDICAL* problem.

THE MEMBERSHIP

I would like to become a member of RESOLVE. Check One:

☐ A. I live in one of the chapter areas indicated above with a star (*). My dues automatically enroll me as a member of both the national organization and the ______________ Chapter. I wish to join as a:
☐ Supporting Member $50. ☐ Contributing Member $40. ☐ Basic Member $30.

☐ B. I live in an area other than those starred. I would like to become a member of National RESOLVE. I wish to join as a:
☐ Supporting Member $45. ☐ Contributing Member $35. ☐ Basic Member $25.
☐ Canadian Member $35. ☐ International $43. (except APO and FPO)

☐ C. I am a professional serving the infertile population.
☐ Professional Member $50.

Services are the same in all categories

☐ D. I am pleased to help RESOLVE by enclosing the additional, tax-deductible contribution of $______________
(Contributions over the Basic Membership fee are tax-deductible and help to support RESOLVE's ongoing work.)

☐ Please send me RESOLVE's most recent National Newsletter. Enclosed is $2.00.

Please send this application with your check payable to RESOLVE, Inc., 5 Water Street, Arlington, MA 02174 (Checks must be in U.S. dollars only)

Name(s) ______________ Phone ______________

Address ______________ City ______________ State ______ Zip ______

RESOLVE's membership list is confidential and never sold, leased, or loaned to any other organization, business or individual. Your membership is activated upon receipt of your membership fee, and RESOLVE services are immediately available to you. Newsletters are published in February, April, June, September and December. Your first newsletter issue serves as RESOLVE's acknowledgement of your member status.

THE NETWORK

The nationwide network of local chapters provides services within easy reach.
(current as of 2/1/89)

Phoenix, AZ*
Tucson, AZ
Los Angeles Cty, CA*
Northern California
Orange County, CA
Colorado
Fairfield County, CT
Greater Hartford, CT
Ft. Lauderdale, FL
Miami, FL*
Atlanta, GA
Savannah, GA*
Boise, ID
Chicago, IL
Indiana*
Iowa
Louisville, KY
Maine
Maryland
Massachusetts*
Michigan
Twin Cities, MN*
Kansas City, MO*
St. Louis,MO*
Nebraska
Central New Jersey
Northern New Jersey
New Mexico
Capital District, NY
Central New York
Long Island, NY
New York City, NY
Rochester, NY
Raleigh/Durham/Chapel Hill, NC*
Ohio*
Tulsa, OK*
Portland, OR
Lancaster, PA
Philadelphia, PA
Pittsburgh, PA
Rhode Island*
Nashville, TN
Central Texas (Austin)*
Dallas/Ft. Worth, TX
Utah
Vermont
Puget Sound (Seattle), WA*
Washington (Metropolitan Area), DC*
Milwaukee, WI*
Northeastern Wisconsin

* Denotes special combined local and national membership

When we first joined RESOLVE, we were trying to learn about both infertility testing and adoption procedures at the same time. We had waited so many years to take the steps that got us to that point and we found great relief in the fact that RESOLVE was a clearinghouse for so much information on both these subjects. RESOLVE had resource people to help us at every step along the way.
Julie Berry
Indianapolis, Indiana

It was at the end of another typical, anxiety-ridden consultation when our specialist handed my husband and me a RESOLVE brochure and told us to call the number. I stuffed the brochure in my purse, and cried all the way home. Six months later, I finally decided to make the call. A very nice woman listened to my story, offered advice and support and gave me information about meetings scheduled by the local chapter. She made me laugh and seemed to understand how I was feeling. I felt I had finally connected with someone who knew what my husband and I were really going through.
Laraine Triplett
Portland, Oregon

RESOLVE, Inc.
5 Water Street
Arlington, MA 02174

Trenton New Mexico Albany
sland New York City Portland
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RESOLVE

WHEN YOU'RE WISHING FOR A BABY . . .

ucson Northern California Ora
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Chicago Indiana Iowa Louisville
nnah Maine Maryland Boston
Minneapolis / St. Paul St. Louis

THE QUESTIONS

When having a baby is taking too long, you may have a medical problem which requires special attention. It may raise questions in your mind, such as:

How do I know if I need to see a specialist?
How do I find a specialist?
What options are available to me?
What medical treatments are most successful?
Am I a good candidate for in vitro fertilization?
Will insurance cover medical treatment?
How do I initiate adoption procedures?
Who can I share my feelings with?
Where can I get more information?

Infertility can be caused by physical problems affecting either or both partners. With proper treatment, your chances of having the child you want are better than ever. And, emotional support can ease anxiety so common in couples seeking help for infertility.

RESOLVE, Inc.
National Office
5 Water Street
Arlington, MA 02174
(617) 643-2424

THE FACTS

What is infertility?

Infertility means that you have been trying to get pregnant for longer than one year or have been unable to carry a pregnancy to term.

Is infertility rare?

No! One in six couples in the U.S. has fertility problems. There are estimated to be over 5 million couples struggling with this problem.

Is infertility a "woman's problem"?

No! The male partner is affected in almost half the cases. It is essential that both the man and woman get tested for infertility.

Is infertility "all in my head"?

No! In 90% of the cases, infertility has an identifiable medical basis. Successful treatment depends upon the nature of the problem. The feelings of stress are the *result* of infertility, *not* the cause.

What kind of help is there?

If you feel discouraged, remember that:

- Improved techniques for diagnosing infertility have made it easier to pinpoint the problem and recommend treatment.
- Medical advances permit safe, effective use of many types of fertility drugs.
- State-of-the-art surgical techniques now make it possible to correct many types of problems.
- Competent counseling provides up-to-date information about a wide variety of alternatives.

THE RESOURCE

RESOLVE is the only nationwide organization for information exchange serving the unique needs of infertile people. Through both the national office and the local chapters, RESOLVE provides access to medical updates, information and referral, and counseling.

RESOLVE offers:
National Services

- the national newsletter, published 5 times yearly
- journal articles and up-to-date fact sheets
- consultation with the medical counselor
- support network of members with similar problems
- advocacy and national media exposure for this important issue
- lists of U.S. infertility specialists and in vitro programs
- monitoring of quality, progressive adoption services
- backing of local efforts for legislative reforms in areas such as insurance coverage for infertility treatment and adoption

Local Chapter Services

- regular programs on medical and emotional issues
- the chapter newsletter and information on local services
- local telephone contact
- doctor referrals
- support groups
- other specialized services such as: referral to therapists and adoption information; resource library; pre-adoptive classes; more...

Tenafly New Brunswick Trenton
Albany Ithaca Long Island New
City Portland Rochester Ohio
Tulsa Lancaster Philadelphia Pit
Nashville Dallas/Ft. Worth Utah
ermont Seattle Washington, DC
Milwaukee Appleton Phoenix
Northern California Orange Cou
orado Fairfield County Greater
Hartford Ft. Lauderdale Miami
Boise Chicago Indiana Iowa Lou
Kansas City Maine Maryland
Minneapolis / St. Paul St. Louis
chigan Nebraska Tenafly New B
nswick Trenton New Mexico

RESOLVE is a nonprofit membership organization established in 1974, with over 50 affiliated volunteer chapters across the country *and* a formal support network of members in areas which have no established chapter.

kee Appleton Phoenix Tucson
Orange County Colorado Fair
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Miami Atlanta Boise Chicago
Iowa Louisville Savannah Maine
aryland Boston Minneapolis St.
Paul St. Louis Michigan Nebr
Tenafly New Brunswick Trento
ew Mexico Albany Ithaca Long
New York City Portland Rochest

RESOLVE, Inc.
National Office
Infertility Counseling Referral Support Groups
5 Water Street Arlington, MA 02174 617/643-2424

RESOLVE is the only national, nonprofit organization serving the unique needs of people struggling with infertility – with over 50 chapters and 15,000+ members.

Literature Available

RESOLVE literature will provide you with new perspectives and in-depth information about your infertility problem. Members are encouraged to take advantage of **RESOLVE** services and the discounts. To speed delivery of your order, send an appropriate-sized, self-addressed envelope to **RESOLVE**, Inc., 5 Water Street, Arlington, MA 02174. Make checks payable (in U.S. dollars only) to **RESOLVE**. Please allow 2-4 weeks for delivery. Prices for U.S. members include postage and handling.

Books

____ *Infertility: A Guide for the Childless Couple*, by Barbara Eck Menning, Prentice Hall Press, 1988.
This new edition, written by **RESOLVE**'s founder, is an excellent resource for anyone experiencing infertility. Members/$9.50 each, Non-members/$10.50 each. Requests originating outside the U.S. except APO or FPO, add $8 additional postage fee (in U.S. dollars only).

____ *Understanding Artificial Insemination: A Guide for Patients*, by William Schlaff, M.D. and Carol Frost Vercollone, L.I.C.S.W., $2.00
A new 20-page booklet on medical and emotional aspects of insemination by husband or donor

Bibliography

Members/$3.00 each Non-members/$5.00 each

Our annotated 14-page bibliography will guide you to all the books and articles on infertility – both the medical and emotional issues. This is updated every 6 months by **RESOLVE**.

____ Please send me the bibliography.

Newsletters

$2.00 Each

Our national newsletters contain a wide range of thought-provoking articles on medical and coping issues.

____ Send me the most recent issue.

____ Send me a set of five recent newsletters ($10.00).

____ Send me the special issue on dealing with family and friends.

Fact Sheets

Members/$2.00 each Non-members/$5.00 each

RESOLVE fact sheets provide detailed, readable, up-to-date information about medical topics and special coping issues.

____ Adoption - Overview
____ Adoption - Private Adoption
____ Artificial Insemination (husband or donor)
____ Childfree Decision-making
____ Clomiphene Citrate (Clomid, Serophene)
____ DES: Its Impact on Infertility
____ Endometriosis
____ HMG (Pergonal) and HCG
____ Immunologic Infertility
____ In Vitro Fertilization/GIFT: Overview
____ Laparoscopy: What to Expect
____ Luteal Phase Defect
____ Medical Management/Male Infertility
____ Microsurgical and Laser Techniques for Tubal Repair
____ Miscarriage: Emotional
____ Miscarriage: Medical
____ Overview of the Infertility Work-up
____ Pinpointing Ovulation
____ Polycystic Ovarian Disease
____ Prolactin Problems (Parlodel)
____ Semen Analysis
____ Stress of Infertility/How to Cope
____ Surrogacy: Overview
____ T-Mycoplasma
____ Understanding Health Insurance
____ Varicocele: Surgical and Medical Treatment
____ What is an Infertility Specialist?

Briefs

Members/$2.00 each Non-members/$4.00 each

Listed below are fact-filled articles from previous newsletters.

Medical Issues

____ Anovulation: (LH-RH pump, Lupron, etc.), 8/88*
____ Cervical Factors, 6/88*
____ DES: Medical and Emotional, 7/88*
____ Ectopic Pregnancy, 4/88*
____ Infections (including chlamydia), 8/88*
____ Laser Laparoscopy, 11/88*
____ Luteal Phase Inadequacies, 11/88*
____ Microsurgery for Vas Blockage and vasectomy reversal, 2/81
____ Monitoring Personal, 8/88*
____ Multiple Miscarriage: Test and Treatment, 6/87
____ Older Women Attempting Pregnancy, 9/87
____ Premature Ovarian Failure, 4/88
____ Preparing for Surgery, 2/87
____ Sperm Washing and I.U.I., 7/86
____ Uterine Structural Factors, 2/88*
____ Zona Free Hamster Egg Test, 4/83

Viewpoints

____ Adoption Perspectives
____ Collected articles on IVF; GIFT
____ Collection on the Male Perspective
____ Coping with Pregnancy after Infertility, 9/80
____ Coping with the Holidays, 12/82
____ D.I. : Collection of Personal Experiences
____ Hysterosalpingograms, 12/88*
____ Infertility as a Chronic Illness, 12/84
____ Meditation and Infertility, 9/88
____ Religious Perspectives and Infertility
____ Secondary Infertility, 4/82, 6/88
____ Sexuality and Infertility, 9/88
____ Surrogating: Personal Experiences, 6/84
____ Views on Patient Rights, 2/86, 2/87

* updated version of previously published article

Order Form

I would like to become a member of **RESOLVE**. Check one:

____ A) I live in one of the 17 chapter areas where the combined annual dues for both local and National RESOLVE as of February 1, 1989 is now:
$50.00 (supporting) ____; $40.00 (contributing) ____; $30.00 (basic) ____*
(Massachusetts; Rhode Island; Miami, FL; St. Louis, MO; Seattle, WA; Ohio; Indiana; Raleigh/Durham/Chapel Hill, NC; Tulsa, OK; Washington, D.C. Metro Area; Phoenix, AZ; Minneapolis/St. Paul, MN; Austin, TX; Los Angeles County; Savannah, GA; Kansas City, KS/MO; Milwaukee, WI)

____ B) I live in an area other than the above. Annual National RESOLVE dues:
$45.00 (supporting) ____; $35.00 (contributing) ____; $25.00 (basic) ____*
$35.00 (Canadian) ____; $45.00 (other International, except APO and FPO) ____

____ C) I am a professional serving the infertile population. $50.00 ____

* Contributions above the Basic membership are tax-deductible and help to support the on-going work of RESOLVE. Services are the same in all categories.

____ I am currently a member of National RESOLVE and am eligible for the literature discount as indicated. *(If you are joining with this form, you are considered a current member.)*

Members, please indicate if the information below is:
change of address ____; change of last name ____

____ I am not a member of National RESOLVE but would like to purchase RESOLVE literature.

Postage: Overseas nonmembers *(except APO and FPO)* add $3 postage for literature other than the Menning book. Postage for Menning book is $8. Literature + Book = $11 postage.

Amount enclosed: Literature $______ + Postage $______ = $__________
Membership = $__________
TOTAL = $__________

Note: If you are becoming a member and ordering literature, *please write two separate checks (in U.S. dollars only)*. This will speed our processing of your requests. *For speedy delivery, please include a self-addressed, manila (9X12) envelope with your order.*

Print Name: ______________________________
Address: ______________________________
City: ______________ State: __________ Zip: __________

B&D

COST AND CONVENIENCE

1. How much does the entire procedure cost, including drugs, per cycle?
2. Do I pay in advance? how much?
3. What are the modes of payment?
4. If applicable, will you submit any bills to my insurance company?
5. How much do I pay if my stimulation cycle is cancelled before egg recovery? before embryo replacement?
6. What are the costs for embryo freezing, storage, and transfer?
7. How much work will I miss? my husband miss?
8. What types of counseling and support services are available?
9. If I must have lodging, is there a low-cost place for me to stay? Do you help arrange this?
10. If I do not get pregnant, when do I make my next office visit for further evaluation and counseling.

The following acronyms and terms are used in this pamphlet:

AFS (The American Fertility Society). An organization of health care specialists interested in reproductive medicine.

GIFT (gamete intrafallopian transfer). The direct transfer of a sperm/egg mixture into the fallopian tube. Fertilization takes place inside the fallopian tube.

IVF (in vitro fertilization). An egg and sperm are combined in a laboratory dish where fertilization occurs. The fertilized and dividing egg is transferred into the woman's uterus.

IVF Registry. An ongoing collection of IVF results from voluntarily participating programs coordinated by the AFS, SART, and Medical Research International.

PROST (pronuclear stage tubal transfer). Egg is fertilized in a laboratory dish and transferred to the fallopian tube before cell division has occurred (pronuclear stage).

SART (the Society for Assisted Reproductive Technology). An affiliated society of the AFS comprised of programs that have demonstrated their ability to perform IVF and GIFT.

TET (tubal embryo transfer). An early stage embryo is transferred to the fallopian tube.

ZIFT (zygote intrafallopian transfer). Egg is fertilized in vitro and the zygote (undivided but fertilized egg) is transferred to the fallopian tube.

This pamphlet presents a partial listing of questions to ask about an IVF/GIFT program. See your physician for further guidance.

For additional copies of this pamphlet, send a self-addressed, stamped business-size envelope to:

The American Fertility Society
2140 11th Avenue South, Suite 200
Birmingham, Alabama 35205-2800

Prepared by The American Fertility Society in conjuction with SART.

QUESTIONS TO ASK ABOUT AN IVF/GIFT PROGRAM

Excerpts from
IVF & GIFT - A Patient's Guide
to Assisted Reproductive Technology

SELECTING AN IVF PROGRAM

When selecting an IVF/GIFT program, information is crucial. Important points to investigate include the qualifications and experience of personnel, types of patients being treated, support services available, cost, convenience, and success rates.

It should be remembered that IVF and GIFT are two separate techniques, and the types of patients accepted into either program influences success rates. Couples over 40, and those with male factor infertility, are less likely to get pregnant than younger couples faced with tubal disease, minimal endometriosis, or unexplained infertility. GIFT is most often used for couples with unexplained infertility and minimal endometriosis and, therefore, may result in a higher pregnancy rate due to the types of patients being treated.

Cryopreservation (freezing) of embryos is available in some IVF/GIFT programs. This offers the possibility of pregnancy beyond the initial treatment cycle. In rare instances a patient can benefit from donor sperm or eggs. In addition to IVF and GIFT, some programs offer other procedures such as combined IVF-GIFT, ZIFT, PROST, TET, etc. These procedures can be considered similar to GIFT.

Older programs have had the opportunity to treat more patients and may have a higher success rate. Although new programs have not yet established long-term success rates, their personnel can be equally qualified. New programs are being established across the country, often in a location more convenient for you.

Credibility is important, too. Does the program adhere to AFS minimal standards? These require IVF/GIFT programs to have on-staff personnel trained in reproductive endocrinology, laparoscopic surgery, sonography, hormone measurement, tissue culture technique, and sperm/egg interaction. Does the program report results to the IVF Registry? Participation is voluntary in this ongoing collection of IVF/GIFT results. The compiled results are published annually in the AFS journal, *Fertility and Sterility*.

The above considerations and answers to the following questions, which focus on a program's recent performance, will help you make an informed decision when choosing an IVF/GIFT program.

SUCCESS RATE

1. When did this program perform its first IVF procedure? first GIFT procedure?
2. How many babies have been born from this program's IVF efforts? GIFT efforts?
3. In the past two years, how many stimulation cycles have been initiated for IVF? for GIFT?
4. In the past two years, how many egg recovery procedures have been done in the IVF program? GIFT program?
5. In the past two years, how many embryo transfer procedures have been done in the IVF program?
6. In the past two years, how many pregnancies have resulted from IVF? from GIFT?
7. In the past two years, how many miscarriages have occurred from pregnancies initiated by IVF? by GIFT?
8. For the past two years, how many live births have occurred in your program from IVF? from GIFT?
9. How many ongoing pregnancies are there from IVF? from GIFT?
10. How many deliveries were twins or other multiple births?

Programs define success in various ways. To most, success is a baby, not a pregnancy. Here are three ways to determine the "take-home baby" rate. The first two equations are based on egg recovery procedures and the third is based on embryo transfers. For IVF or GIFT, divide live births (question 8) by egg recovery procedures (question 4); or, add live births (question 8) to ongoing pregnancies (question 9) and divide the sum by egg recovery procedures (question 4). In the latter equation, which can be applied to the most recent results of a program, you are assuming the ongoing pregnancies will result in live births. For IVF, divide live births (question 8) by embryo transfers (question 5).

DETAILS ABOUT THE PROGRAM

1. Does the program meet AFS minimal standards?
2. Does the program report its results to the IVF Registry?
3. Is the program a member of SART?
4. How many doctors will be involved in my care?
5. Is one or more doctors board certified in Reproductive Endocrinology?
6. To what degree can my own doctor participate in my care?
7. Whom do I call day or night if I have a problem?
8. Do you freeze embryos (cryopreservation)?
9. Is donor sperm available in your program? Are donor eggs?
10. Do you have an age limit?

(over)

INVESTIGATION OF THE INFERTILE COUPLE

THE AMERICAN FERTILITY SOCIETY
FOUNDED 1944

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THE AMERICAN FERTILITY SOCIETY

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INVESTIGATION OF THE INFERTILE COUPLE

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INTRODUCTION

Eighty percent of couples attempting pregnancy achieve a conception within one year with regular intercourse of reasonable frequency. An additional ten percent achieve conception by the end of the second year. Ten percent will remain infertile at the end of two years.

In the 1976 National Survey of Family Growth, 25.3 percent, or 6,954,000 of all married couples with the wife of childbearing age were classified as having a fecundity impairment. Many of these couples, however, did not desire children or additional children.

The increased incidence of pelvic inflammatory disease with the use of intrauterine devices may increase the number of infertile women, but the decrease in pelvic inflammatory disease found with the use of oral contraceptives may counterbalance this trend.

Female factors in infertility account for approximately forty to fifty percent of the cases. Forty percent involve male factors, and the remainder involve problems in both members of the couple. Approximately twenty to thirty percent of the problems on the female side are tubal in origin, and fifteen percent are ovulatory problems, five percent cervical, and in ten to twenty percent the cause is unknown.

INFERTILITY INVESTIGATION

Any couple desiring children who does not achieve a pregnancy within two years of adequate exposure should have a systematic evaluation of their reproductive function. The investigation should be performed for women thirty years of age or older after one year of exposure. Earlier investigation may be recommended in younger women because of their own concerns or because of factors in their history or physical examination, which suggests the presence of an abnormality in the reproductive function. The success rate for treatment of infertility declines with length of infertility and increasing age; hence adequate investigation and treatment, if indicated, should not be unnecessarily postponed.

Steps in the investigation should be outlined to the couple together, if possible. The investigation should, in most cases, be completed within three to six months, and prolonged investigation or basal temperature determinations should be avoided, if possible, to avoid undue psychic stress.

The sequence in which infertility tests should be performed may be determined by history or physical findings, which suggest looking at one or another factor first. The specific tests will be discussed in the following sections.

The semen analysis should be obtained early in the investigation (details to be discussed later), as a major defect on this one test may obviate doing any further testing on the female.

STUDY OF THE FEMALE

I. History:

A. Duration of infertility: Length of contraceptive and non-contraceptive exposure.

B. Fertility in other marriages of self or spouses.

C. Obstetric: (1) number of pregnancies and abortions;
(2) length of time required to initiate each pregnancy;
(3) complications of any pregnancy;
(4) duration of lactation.

D. Gynecologic: detailed menstrual history and leucorrheal history.

E. Previous tests and therapy done for infertility.

F. Medical: General medical history including chronic and hereditary diseases.

G. Surgical: Especially abdominal or pelvic surgery.

H. Sexual history in detail: Libido, orgasm capacity, techniques, frequency of intercourse, and post-coital practices.

I. Psychosomatic evaluation: (a) general; (b) as regards infertility problem, particularly her reason for seeking advice at this time.

II. **Physical Examination:**

A. General: Careful examination of other organs and parts of the body. Special attention given to habitus, fat, and hair distribution, acne.

B. Genital tract: State of hymen re: full penetration; clitoris; vaginal infection, including trichomoniasis and candidiasis; cervical tears, polyps, infection, patency of os, accessibility to insemination; uterine size, position and mobility; adnexa, tumors, evidence of endometriosis.

III. **Laboratory Data:**

A. Routine urine, complete blood count, and serologic test for syphilis. Additional laboratory studies may be done as indicated.

B. Basic endocrine studies are indicated in patients with irregular menstrual cycles or in amenorrhea, hirsutism, acne or excessive weight gains.

ANOVULATION	**AMENORRHEA**
Prolactin	Prolactin
T-3, T-4, TSH	FSH & LH
DHEA-S	T-3, T-4, TSH
Testosterone	DHEA-S

Endometrial biopsy
Serum Progesterone

Glucose Tolerance
Test (if indicated)
Lateral x-ray of Skull
(if indicated)

Buccal smears and
chromosomal studies
(Primary Amenorrhea)
Glucose Tolerance
Test (if indicated)
Endometrial biopsy
(if indicated)
CAT Scan of the sella
(if indicated)

There are other laboratory tests that may be added as desired for a more complete diagnosis of endocrine problems.

C. Sperm antibody agglutination studies. These are special laboratory procedures which may be indicated when semen analysis and cervical mucus appear normal, but no motile sperm are found at properly timed postcoital testing.

STUDY OF THE MALE

I. History:

A. Has his fertility been established? With present spouse? Other women?

B. Medical: General medical history including sexually transmitted diseases, epididymitis, mumps orchitis, chronic diseases, prescription or other drugs, recreational drugs (e.g. marijuana, alcohol, et cetera) recent febrile episode.

C. Surgical: Herniorrhaphy, injury to testes, other surgery in genital area.

D. Occupational: Exposure to chemicals, x-ray, radar or extreme thermal changes. Physical nature of occupation. Vacations and work habits.

E. Previous tests and therapy done for study of infertility.

F. Duration of infertility.

G. Sexual history: Onset of puberty, coital habits, does ejaculation take place, et cetera. Status of libido and sexual potency.

II. Physical Examination:

A. General examination: Blood pressure, status of general health. Evaluate degree of androgenicity.

B. Reproductive system: Penis, position of urethral opening, measure testicular size (exclude epididymis – normal 3.6-5.5 (average 4.6) x 2.1-3.2 cm. (average 2.6)), Testicular and epididymal consistency, presence of vas deferens; prostate size and consistency. Careful search for varicocele – this evaluation should be performed in upright position – in small varicoceles reflux of blood flow during valsalva maneuver may be the only physical sign.

III. Laboratory Data:

A. Routine urinalysis, complete blood count, fasting SMAC profile (blood chemistries, including glucose, triglycerides, liver function, et cetera), serological test for syphilis.

B. Complete seminal fluid examination by experienced laboratory.

C. Additional laboratory studies may be performed as indicated.

  (1) Basic endocrine studies are indicated in patients with azoospermia or severe oligospermia or low volume ejaculate and/or decreased androgenicity.
    a. Serum FSH and LH titers
    b. Serum testosterone
    c. Serum prolactin

  (2) Special tests depending on history, physical examination, and seminal fluid findings.
    a. Lateral skull x-rays of sella turcica
    b. Buccal smears
    c. Chromosomal studies of peripheral blood
    d. Seminal fluid fructose (presence of azoospermia, and testes within normal range for size). Absence of fructose suggests congenital absence of seminal vesicles and/or portions of ductal system.

IV. Testicular Biopsy:

Where correct interpretation of a testicular biopsy is available, this may be a procedure that will give a more accurate diagnosis and prognosis in cases of azoospermia and severe oligospermia.

FLOW SHEET OF INFERTILITY INVESTIGATION

NAME: ______________________________ CHART # ______________

DURATION OF INFERTILITY –
Primary or secondary

PAST HISTORY (PERTINENT FACTS)
Obstet. –
Surgical –
Ch. illnesses (allergies) –
Nutrition –

MENSTRUAL HISTORY –
Interval –
Amenorrhea –

SEXUAL HISTORY – FREQUENCY OF INTERCOURSE –

GENERAL PHYSICAL EXAM – Ht. __________ Wt. __________
Abnormalities –

PELVIC EXAM –
Abnormalities –

BASAL TEMPERATURE – *Monophasic* *Biphasic* *Equivocal*

OVARIAN FUNCTION –
Endometrial biopsy *Serum progesterone* *Laparoscopic observation*

TUBAL PATENCY –
Rubins Test *Hysterosalpingogram* *Laparoscopy*

UTERUS –
Hysterogram
Hysteroscopy
Abnormalities at laparoscopy

CERVIX –

Mucus –	Normal		Abnormal
Post-coital test –	No. sperm/hpf –		% motile –
	"Shaking" sperm –		
	Progressive sperm –	>5 <5	
Immunologic (If indicated) –			Izojima Kilbrick Franklin-Dukes

LAPAROSCOPIC FINDINGS –

ADDITIONAL ENDOCRINE STUDIES (if indicated) –

Prolactin –	Thyroid tests –
FSH –	Adrenal tests –
LH –	Glucose tolerance –

MALE

HISTORY (PERTINENT) –

Children –	Jockey shorts –
Surgical –	Hot tub baths –

PHYSICAL EXAM – Ht. _______ Wt. _______ BP _______

General health –
Urinalysis –
Urologic abnormalities –

SEMEN ANALYSIS	DATE	DATE
Volume –		
Count/cc. –		
Motility (%) –		
Abnormal cells (%) –		
WBCs –		

ENDOCRINE FACTORS IN FEMALE INFERTILITY

The hallmark of normal female reproductive endocrinologic function is ovulation. Disorders of ovulation account for 10-15% of all infertility problems. This includes luteal phase dysfunction, anovulation, and amenorrhea. One of the initial steps in the evaluation of infertile couples should be the demonstration of normal ovulation. Women who have menstrual periods at monthly intervals in a regular fashion and also have premenstrual molimina (breast tenderness, fluid retention, irritability) as well as functional dysmenorrhea, are usually ovulatory, but not always, and therefore some test of ovulation is necessary.

Tests of Ovulation

The Basal Body Temperature (BBT) Chart

The BBT chart can provide indirect evidence of ovulation, but often requires confirmation by an additional method of evaluation. The temperature can be taken orally with a regular thermometer. Special BBT thermometers show a range of only a few degrees and are easier to read, but they are unnecessarily expensive. The temperature is best taken immediately upon awakening, before any activity, and recorded for that date on a graph, reading the closest tenth of a degree.

The chart should be started on the first day of a cycle and reviewed after the next menstrual period. Characteristically, the basal body temperature prior to ovulation is in the 97.2° - 97.4°F range, and after ovulation the basal temperature is over 98°. The chart is very helpful when it is clearly biphasic. Sustained elevation of temperature of less than 10 days duration suggests, but is not diagnostic of, luteal dysfunction. A monophasic level throughout the cycle suggests anovulation. A slow rise in a biphasic chart is not an indication of a hormone abnormality. When the chart is unclear, another method of evaluation must be used.

The exact day of ovulation is difficult to pinpoint. A significant increase in temperature is not noted until 2 days after the LH peak, coinciding with a rise in peripheral levels of progesterone to greater than 4 ng/ml. Physical release of the ovum probably occurs on the day prior to the time of the first temperature elevation. This may or may not be marked by a dip in the temperature to the lowest level of the cycle. A sensible schedule for coitus is every 36-48 hours in a period encompassed by 3-4 days prior to, and including 2-3 days after expected ovulation. It is unwise, however, to suggest rigid adherence to a schedule linked to the BBT, as this may produce significant psychologic stress, sufficient to inhibit sexual relations.

ENDOMETRIAL BIOPSY

The endometrial biopsy should be timed to the latter part of the menstrual cycle, preferably 2-3 days prior to the expected period. Bimanual pelvic examination is necessary to determine the uterine position and to exclude pregnancy. The cervix is cleansed with an antiseptic and a tenaculum is attached to the anterior cervix. A single biopsy is obtained, being sure to be significantly beyond the endocervical canal. The biopsy should not be repeated multiple times unless there is difficulty in obtaining a sufficient sample of tissue. Premedication with an inhibitor of prostaglandin synthesis may be used to minimize cramping, but the cramping is usually of short duration and only modest in intensity. While premenstrual biopsy may present the possibility of interrupting a pregnancy, this possibility is very remote. Biopsy during menstrual bleeding is usually associated with such fragmentation of the endometrium that precise interpretation is difficult.

The endometrium should be dated by an individual familiar with the criteria outlined by Noyes, et al. The dated biopsy should be compared to cycle length according to the date of the onset of the next menses. Luteal dysfunction is diagnosed if the development of the endometrium lags behind the cycle day by more than 2 days. Proliferative endometrium is diagnostic of anovulation.

PROGESTERONE

A serum progesterone value of 3-4 ng/ml or greater is indicative of ovulation. However, values at the midluteal phase are usually 10 ng/ml or more. Correlation of serum progesterone levels with dating of the endometrial biopsy is not good. In addition, progesterone is secreted in episodic fashion leading to significant variation in random samples. The basal body temperature chart and the endometrial biopsy, therefore, are better methods to evaluate ovulation.

ASSESSMENT OF ABNORMAL OR ABSENT OVULATION

Luteal Dysfunction

An inadequate luteal phase is due to a relative deficiency in secretion of progesterone by the corpus luteum. An inadequate luteal phase can be found in isolated cycles of normal women, therefore, this problem must be identified repetitively in order to consider it as a significant factor in infertility. Although only 3-4% of infertile women have an inadequate luteal phase, the diagnosis should be considered in women with normal cycles and unexplained infertility, in women with a short luteal phase on basal body temperature charts, and in women with a history of repetitive abortions.

The underlying causes of this problem can be multiple. A careful search for galactorrhea and elevated prolactin levels is important in that, if found, the treatment of choice is bromocriptine suppression of prolactin secretion. Either hyperthyroidism or hypothyroidism can be associated with subtle abnormalities of ovulation. Mild or compensated abnormal thyroid secretion can be clinically undetectible. Therefore, the most cost effective screen for thyroid disease is the measurement of the circulating levels of TSH and free T4. Other common causes of luteal dysfunction are either excessive body weight or an underweight condition due to abnormal eating patterns or excessive exercise. Most often, however, the cause of luteal dysfunction is not apparent. In the latter cases, treatment is effective with either clomiphene or exogenous progesterone.

ANOVULATION

Persistent anovulation is associated with the development of polycystic ovaries. Because there are many causes of anovulation, there are many causes of polycystic ovaries. Laboratory assessment should include prolactin levels, thyroid function (TSH and free T4), and endometrial biopsy if the anovulation has been long standing. The association between anovulation and abnormal endometrial changes should be kept in mind, and, in this situation, endometrial biopsy should be performed utilizing extensive sampling by one of the office aspiration curettage methods. While an elevated LH value in the presence of a low or low-normal FSH may be characteristic of this clinical condition, the diagnosis is easily made by the clinical presentation alone. The routine measurement of FSH and LH levels in anovulatory patients is not cost-effective.

Evaluation of androgen production is not necessary if there is no hirsutism or virilization. But adrenal hyperfunction can present with abnormal ovulation. Usually, however, adrenal disease can be indicated in a careful history. Tumors which produce androgens are very rare, and usually are noted by the rapid progression of masculinization over several months.

Laboratory assessment for excess androgen production includes the measurement of blood levels of testosterone and dehydroepiandrostereone sulfate (DS). When clinical suspicion is high, a screen for Cushing's syndrome is indicated. The single dose overnight dexamethasone test is excellent. Dexamethasone (1 mg) is given orally at bedtime, and blood is drawn at 8 the next morning for a plasma cortisol. A value less than 6 ug/dl rules out Cushing's syndrome.

The upper limit of normal for DS in most laboratories is 250 ug/dl. When DS is normal, adrenal disease is most unlikely; however a moderately elevated DS is commonly found in anovulatory patients with polycystic ovaries. Clinical experience has established that a DS level below 700 ug/dl does not require further evaluation.

The total testosterone concentration is often in the normal range in a woman who is hirsute because the binding globulin levels are depressed. It is not necessary, however, to measure the free (unbound) testosterone because the purpose of the total testosterone assay is to screen for testosterone-secreting tumors which are associated with testosterone levels in the male range (over 200 ng/dl).

Both DS and testosterone can be increased in association with hyperprolactinemia, and both return to normal with prolactin suppression by bromocriptine. This underscores the need to search for galactorrhea and to obtain a prolactin level in all women with abnormal or absent ovulation.

AMENORRHEA

Evaluation of amenorrhea begins with the history and physical examination. The clinician should seek the following: evidence for psychological dysfunction or emotional stress, family history of apparent genetic anomalies, signs of a physical problem with a focus on nutritional status, abnormal growth and development, and evidence of CNS disease. As with any woman who does not ovulate normally, the initial laboratory assessment should include a prolactin level and measurement of thyroid function (TSH and free T4). The patient should be given a progestational challenge and if bleeding is induced, the diagnosis is anovulation, and management can be immediately planned. If bleeding fails to take place, the functional capacity of the uterus should be assessed with a sequential course of estrogen and a progestin. This step can be omitted if there is no historical reason (infection or trauma such as a curettage) to suspect an end organ problem. Finally, the presence or absence of ovarian failure must be documented by measuring the blood levels of FSH and LH.

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TUBAL AND PERITONIAL FACTORS

Tubal Factor

Classification of Tubal Disease

A major difficulty in comparing different series of surgical procedures is the lack of universally accepted classification of tubal surgery. A Committee of the International Federation of Fertility Societies introduced a classification which was further modified by the same Committee at the 10th World Conference of Fertility and Sterility. Success of tubal surgery depends upon the extent of adhesion formation around the tube, the condition of the fimbrial ends of the fallopian tube, and the extent to which the endosalpinx of the oviduct has been damaged. Microsurgical techniques to repair the fallopian tube under magnification may enhance overall pregnancy success. However, when the tube is severely damaged, microsurgery offers no advantage. The physiologic function of the severely damaged tube is, in most instances, irreversably altered.

Peritoneal Factors

This factor is caused by a disturbance in the peritoneal lining of the abdominal cavity that interferes with the transfer of the egg from the ovary, at the time of ovulation, to the tubal ostium, or endometriosis. These disturbances are usually adhesions resulting from trauma (surgery, pelvic injuries), from chronic inflammatory processes (infected abortions, ruptured appendix, mesenteric lymphadenitis, gonorrhea).

Clues to the diagnosis of this factor may be suggested by the history and by findings during the physical examination (especially pelvic and rectal examination). In some instances the presence of pelvic tumors or masses will permit a presumptive diagnosis where pelvic surgery may be decided upon without further evaluation. In such patients, however, an intravenous pyelogram and radiographic study of the large intestine should be performed.

In other patients who have had adequate basic studies, the findings may be negative. These patients constitute a sizeable portion of the apparent "normal infertile couple." These patients should be investigated by endoscopy, usually laparoscopy. Endoscopic examination is invaluable in the diagnosis of obscure infertility problems in the female. Directions for the use of this procedure are outlined in numerous articles and textbooks. Various reports have indicated that when the usual basic investigative studies failed to show any pelvic abnormality, the endoscopic examination will reveal a definitive cause for the infertility in a significant proportion of patients. Therefore, the importance of endoscopic procedure in the investigation of the infertile female is the single most important diagnostic procedure.

Endometriosis

A diagnosis may be suggested by the history, corroborated by the pelvic examination and verified by endoscopy. In order to properly evaluate the results of either surgery or hormonal therapy, the extent of the endometriotic process should be described and classified in accordance with the classification proposed by The American Fertility Society.

There is a definite correlation between the extent of endometriosis and subsequent fertility after treatment with a therapeutic modality. Approximately 30-40% of women with infertility have endometriosis. However, only 30% of women with endometriosis are infertile. Thus, there are some women with endometriosis who will conceive without treatment.

Study of the Infertile Couple

The exact pathologic cause of infertility is unknown. The fallopian tubes are rarely involved with endometriosis. In most instances, the infertility evaluation is completely normal except for the presence of endometriosis. If so, endometriosis may be an important factor responsible for infertility.

The diagnosis of endometriosis may be suggested by history, corroborated by pelvic examination and verified by endoscopy. Treatment for endometriosis should only be instituted with a precise diagnosis. Documentation of the presence of disease may be performed by photography or by a direct biopsy. There are three forms of treatment for endometriosis:

(1) Expectant
(2) Hormonal
(3) Surgical.

It is generally felt that roughly 20-30% of women will conceive if no therapy is instituted. This may be higher for milder forms of the disease. Hormonal therapy consists of progesterone, danazol, or gonadotropin-releasing hormone analogs. Pregnancy after treatment with the various forms of hormonal therapy range between 30 and 70% depending upon the extent of the disease. Finally, the surgical removal, fulguration, and/or vaporization of endometrial tissue has been suggested especially in patients with moderate or severe disease. Pregnancy success after surgery has been reported between 30 and 75% depending upon the extent of the disease. Selection of particular therapeutic modality must take into account the patients age, duration of infertility, and associated pelvic pathology.

THE EVALUATION OF TUBAL AND PERITONEAL FACTORS

DIAGNOSTIC PROCEDURES

Uterotubal Insufflation

A. Indication: A screening method used to determine patency of tubes.

B. Contraindication: Possible pregnancy, uterine bleeding, recent curettage or infections of the genital tract.

C. Time of cycle: Any day between complete cessation of menses and ovulation. Practically, this means days 6 to 12 in cycles of usual length, counting the first day of the menses as day one.

D. Technique: (Mild sedative or tranquilizer given before the test may allay apprehension of patient).

(1) After bimanual pelvic examination to determine position of fundus, insert speculum, expose cervix.

(2) Insert uterine cannula into cervical canal. Hold cannula snugly against cervix. Preferably, do not use tenaculum forceps unless needed to prevent leakage of gas between cannula and cervix. Most tests may be done without use of a tenaculum and will result in less tubal spasm.

An alternate method is to insert a #12 Foley catheter into the uterine cavity and inflate the bag with 1½ to 2½ cc. of water to the point of beginning discomfort. Most patients have less discomfort with this rubber tube than with the metal cannula. The tip of the metal cannula pushed into the distal end of the #12 Foley catheter makes an easy connection to the gas apparatus.

(3) Admit CO_2 according to directions of the machine you use.

(4) Maximum pressure on first test should not exceed 150 mm. Hg. Maximum pressure should not exceed 200 mm. Hg. at any time.

(5) Auscultate abdomen suprapubically for sound of passing gas.

(6) Shoulder pain should occur after arising if the tubes are patent. If shoulder pain should occur, immediately put patient in knee-chest position and pain will disappear if patient is left for 4-5 minutes.

(7) A kymograph may be used for a permanent record. Always use CO_2. The use of air is dangerous as it may result in air embolism.

Hystero-Salpingography

Often preferred in lieu of uterotubal insufflation because of its greater accuracy. It is especially valuable to diagnose uterine abnormalities, intrauterine lesions, or to confirm suspected proximal tubal occlusion.

A. Indications:
  (1) Often used as an initial diagnostic procedure before proceeding to laparoscopy.
  (2) Yields information on tubal patency and on the site of tubal obstruction, if present.
  (3) Useful in the diagnosis of uterine congenital malformation or intrauterine lesions such as endometrial polyps, submucous myomas and adhesions.
  (4) Helpful in delineation of the cervical canal when cervical incompetence is suspected.
  (5) Oil media may have a therapeutic effect; that is, promote pregnancy in a subsequent cycle.

B. Contraindications: Possible pregnancy, uterine bleeding, acute pelvic inflammatory disease, recent uterine instrumentation, and allergy to iodine.

C. Technique:
  (1) Medium must be a sterile radiopaque medium. If oil is used, bottle must be immersed in warm water until material is in a completely fluid state.
    (a) Oil media
    Disadvantage: Oil media such as lipiodol may cause lipid granulomas. This complication is less likely with iodochlorol.
    (b) Water soluble sinografin, medopaque, skiodan acacia
    Disadvantage: Tubal outline occasionally indistinct because of rapid spill into the pelvis.
  (2) Procedure:
    (a) Prepare instruments and patient as for tubal insufflation (see above). Determine that cannula is empty of air by filling it with radiopaque material before inserting it into the cervical os. Leakage may be prevented by using a two-way stop-cock attached to a 10 cc. Luer-lok syringe.
    (b) Take a preliminary film of the pelvic area as a "scout film" to look for previous media or other artifacts.
    (c) The injection phase of the procedure is best done under fluoroscopic control. When a fluoroscopic screen is not available, radiographs are taken sequentially as outlined below. When filling can be visualized on a fluoroscopic screen, radiograms are taken at appropriate times to provide a permanent record of the findings.
    (d) Inject 1-2 cc. and take first film immediately. This will reveal the outline of the uterine cavity alone, as tubes are frequently not outlined with so small an amount of media. This film will reveal any abnormality of the uterus itself, such as congenital malformation, endometrial polyp, submucous fibroid or uterine synichiae.

(e) For complete visualization of the uterus and tubes, a total of 4-8 cc. of radiopaque material may be necessary, depending upon the size of the uterus. After injecting the extra 3-5 cc., additional films are made. These should determine whether or not the tubes are patent. When blockage at or near the uterotubal junction is suspected, hysterosalpingography should be repeated or the diagnosis confirmed by laparoscopy before a surgical procedure is considered.

(f) When using radiopaque oil, withdraw as much of the material as possible at the completion of the test. This may reduce the likelihood of oil granulomas.

(g) Visualization of the cervical canal is usually obtained during the above procedure, usually following removal of the instruments.

D. Complications: Pain, perforation, hemorrhage, granuloma formation, acute flare of pelvic inflammatory disease, allergic reactions, intravasation and endometriosis.

Hysteroscopy

A. Indications: To evaluate anatomic abnormalities of the uterine cavity.

B. Contraindications: Infection, bleeding, intrauterine pregnancy, cervical malignancy, and recent instrumentation of the uterine cavity.

C. Time of Cycle: Any day between the cessation of menses and prior to ovulation.

D. Techique:

(1) High molecular weight Dextran 70 in dextrose (Hyskon Pharmacia Laboratories, Piscataway, New Jersey) is an optically clear fluid with a high refractive index. It is an electrolyte-free, nonconductive medium, with an average molecular weight of 70,000. This nontoxic biodegradable medium provides excellent visualization. CO_2 gas insufflation has been utilized for hysteroscopy, although there are added risks of possible gas intravasation with secondary hypercarbia and acidosis.

(2) Hysteroscopy may be performed either under general anesthesia or with a pericervical block and mild analgesia.

(3) The endocervical canal and uterine cavity are carefully sounded to determine if dilatation of the internal os is necessary. An obturator is carefully inserted into the level of the internal os, the insert removed and the hysteroscope introduced and fixed with the encasing sheath. Exploration of the uterine cavity is then performed while the transparent medium is inserted. Due to the foroblique vision of most

endoscopes, a slight rotation motion may be necessary.

(4) The uterine cavity is systematically examined and the cervical canal thoroughly inspected as the hysteroscope is being withdrawn. A systematic recording of hysteroscopic findings is essential. Endoscopic photography or video recording may provide further documentation of findings.

(5) Operative hysteroscopy provides a useful method for removal of imbedded uterine device, endometrial polyps and/ or lysis of intrauterine synechiae. The resection of intrauterine septi and the removal of small submucous myomas may be accomplished through the hysteroscope or a resectoscope.

E. Complications: Pain, bleeding from cervical laceration or uterine perforation, infection, endometriosis, anesthesia risks, complications related to the medium.

(1) Dextran: Cardiovascular overload with intravenous infusion of Dextran.

(2) CO_2: Acidosis arrhythmia with possible embolus.

Laparoscopy

A. Indication: A surgical procedure to determine the condition of the pelvic structures, ie. pelvic peritoneum, uterus, tubes and ovaries.

B. Contraindication: Possible pregnancy, uterine bleeding, a large pelvic abdominal mass, ventral hernia, multiple previous operative procedures, severe cardiac or respiratory disease.

C. Time of Cycle: Any day between the complete cessation of menses and ovulation to avoid the interruption of an unexpected pregnancy and/or possible damage to a newly formed corpus luteum. Laparoscopy may be carried out in the post ovulatory phase, however, the couple should be instructed to use contraceptives, or to avoid intercourse in this cycle of the study. An advantage to a postovulatory laparoscopy is that the corpus luteum and stigma may be actually viewed, thus confirming ovulation.

D. Technique: Procedure may be performed under local or general anesthesia with the patient in the lithotomy position.

(1) A bimanual pelvic examination is performed to determine the position of the fundus.

(2) The cervix is then exposed and a uterine cannula is attached to the cervix for a manipulation. There are many types of manipulators which can be applied to manipulate the uterus and through which indigo carmine dye may be injected to assess tubal patency during laparoscopy.

(3) A small incision is made in the umbilicus through which a needle is placed and 2½ - 3 liters of carbon dioxide may be placed in the abdomen.

(4) The larger trocar is inserted through which the laparoscope is inserted and the pelvic organs viewed. Second puncture

system may be necessary to properly expose the pelvic viscera. This is particularly useful for viewing the underside of the ovary and ovarian fossa. A second puncture is very helpful when performing operative laparoscopy.

(5) Tubal pertubation with indigo carmine dye should be performed at the time of laparoscopy to confirm tubal patency. The presence or absence of tubal occlusion can be appreciated with the injection of dye through the cannula placed into the cervix. Manipulation of the uterus and adnexal structures will usually permit accurate examination of the fimbria near the end of the fallopian tube and the appreciation of the presence of fimbrial agglutination as well as perifimbrial adhesions.

(6) Laparoscopic findings should be carefully recorded. Photography and/or video recording may be used to document all findings.

E. Adjunctive Techniques: Lysis of adhesions, biopsy of pelvic peritoneum may be performed through the laparoscope. With special training, operative laparoscopy may be performed. Applications of electrocautery and/or laser requires special training. These procedures may be used to eliminate implants of endometriosis and adhesions. Operative laparoscopy may also be used to remove tubal pregnancies and/or perform distal tubal surgery.

Laparoscopy is an operative procedure associated with risks and complications. Pelvic infection, bleeding, anesthesia, and damage to the intestine, bladder or vessels has been reported among the complications of laparoscopy. These complications, as well as those of general anesthesia itself, should be thoroughly reviewed with the patient and weighed in their decision as to whether or not to proceed with this diagnostic measure.

Table 1
Classification of Tubal Procedures[a]

1. Lysis of Periadnexal Adhesions (Salpingolysis-Ovariolysis): Classified According to Adnexa with Least Pathology
   a. Minimal: 1 cm of tube or ovary involved
   b. Moderate: partially surround tube or ovary
   c. Severe: encapsulating peritubal and/or periovarian adhesions
2. Lysis of Extra-adnexal Adhesions
   a. Minimal
   b. Moderate
   c. Severe
3. Tubouterine Implantation
   a. Isthmic: implantation of isthmic segment
   b. Ampullary: implantation of ampullary segment
   x. Combination: different type implantation on right and left sides
4. Tubotubal Anastomosis
   a. Interstitial (intramural)-isthmic
   b. Interstitial (intramural)-ampullary
   c. Isthmic-isthmic
   d. Isthmic-ampullary
   e. Ampullary-ampullary
   f. Ampullary-infundibular (fimbrial)
   x. Combination: different type anastomosis on right and left tubes
5. Salpingostomy (Salpingoneostomy): Surgical Creation of a New Tubal Ostium
   a. Terminal
   b. Ampullary
   c. Isthmic
   x. Combination: different type salpingostomy on right and left tubes
6. Fimbrioplasty: Reconstruction of Existent Fimbriae
   a. By deagglutination and dilatation
   b. With serosal incision (for completely occluded tube)
   x. Combination: different type fimbrioplasty on right and left tubes
7. Other Reconstructive Tubal Operations (specify)
8. Combination of Different Types of Operations
   a. Bipolar: for occlusion at both proximal and terminal end of tube (specify)
   b. Bilateral: different operations on the right and left sides (specify)

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[a] From the Ad Hoc Committee of the International Federation of Fertility and Sterility.

THE AMERICAN FERTILITY SOCIETY
REVISED CLASSIFICATION OF ENDOMETRIOSIS

Patient's Name ______________________________ Date ______________________

Stage I (Minimal) - 1-5
Stage II (Mild) - 6-15
Stage III (Moderate) - 16-40
Stage IV (Severe) - >40
Total ______________

Laparoscopy ________ Laparotomy ________ Photography ________
Recommended Treatment ______________________________

Prognosis ______________________

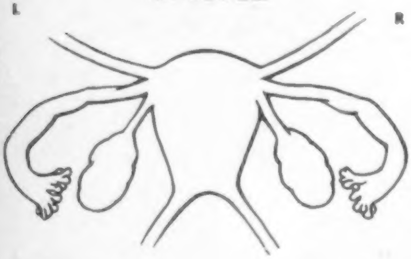
PERITONEUM	ENDOMETRIOSIS	<1cm	1-3cm	>3cm
	Superficial	1	2	4
	Deep	2	4	6
OVARY	R Superficial	1	2	4
	Deep	4	16	20
	L Superficial	1	2	4
	Deep	4	16	20
	POSTERIOR CULDESAC OBLITERATION	Partial		Complete
		4		40
	ADHESIONS	<1/3 Enclosure	1/3-2/3 Enclosure	>2/3 Enclosure
OVARY	R Filmy	1	2	4
	Dense	4	8	16
	L Filmy	1	2	4
	Dense	4	8	16
TUBE	R Filmy	1	2	4
	Dense	4*	8*	16
	L Filmy	1	2	4
	Dense	4*	8*	16

*If the fimbriated end of the fallopian tube is completely enclosed, change the point assignment to 16.

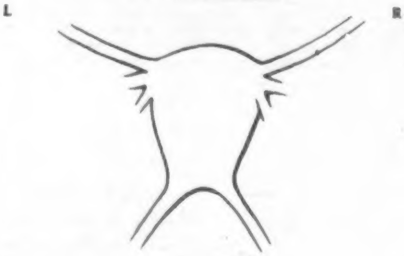
Additional Endometriosis: ______________________________

Associated Pathology: ______________________________

To Be Used with Normal
Tubes and Ovaries



To Be Used with Abnormal
Tubes and/or Ovaries



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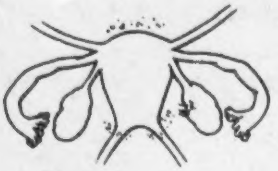
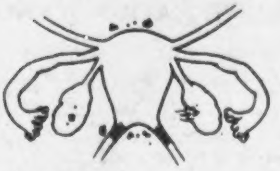
EXAMPLES & GUIDELINES

STAGE I (MINIMAL)



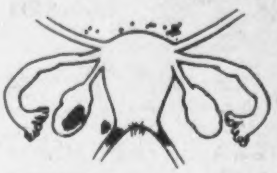
PERITONEUM			
Superficial Endo	–	1-3cm	· 2
R. OVARY			
Superficial Endo	–	< 1cm	· 1
Filmy Adhesions	–	< 1/3	· 1
TOTAL POINTS			4

STAGE II (MILD)



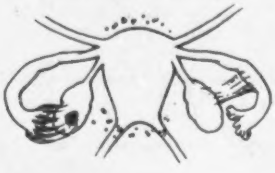
PERITONEUM			
Deep Endo	–	> 3cm	· 6
R. OVARY			
Superficial Endo	–	< 1cm	· 1
Filmy Adhesions	–	< 1/3	· 1
L. OVARY			
Superficial Endo	–	< 1cm	· 1
TOTAL POINTS			9

STAGE III (MODERATE)



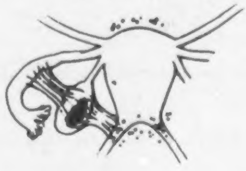
PERITONEUM			
Deep Endo	–	>3cm	· 6
CULDESAC			
Partial Obliteration			· 4
L. OVARY			
Deep Endo	–	1-3cm	· 16
TOTAL POINTS			26

STAGE III (MODERATE)



PERITONEUM			
Superficial Endo	–	> 3cm	· 4
R. TUBE			
Filmy Adhesions	–	< 1/3	· 1
R. OVARY			
Filmy Adhesions	–	< 1/3	· 1
L. TUBE			
Dense Adhesions	–	< 1/3	· 16*
L. OVARY			
Deep Endo	–	< 1 cm	· 4
Dense Adhesions	–	< 1/3	· 4
TOTAL POINTS			30

STAGE IV (SEVERE)

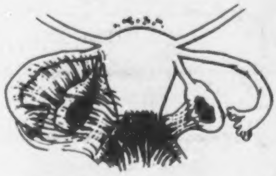


PERITONEUM			
Superficial Endo	–	> 3cm	· 4
L. OVARY			
Deep Endo	–	1-3cm	· 32**
Dense Adhesions	–	< 1/3	· 8**
L. TUBE			
Dense Adhesions	–	< 1/3	· 8**
TOTAL POINTS			52

*Point assignment changed to 16

**Point assignment doubled

STAGE IV (SEVERE)



PERITONEUM			
Deep Endo	–	>3cm	· 6
CULDESAC			
Complete Obliteration			· 40
R. OVARY			
Deep Endo	–	1-3cm	· 16
Dense Adhesions	–	<1/3	· 4
L. TUBE			
Dense Adhesions	–	>2/3	· 16
L. OVARY			
Deep Endo	–	1-3cm	· 16
Dense Adhesions	–	>2/3	· 16
TOTAL POINTS			114

Determination of the stage or degree of endometrial involvement is based on a weighted point system. Distribution of points has been arbitrarily determined and may require further revision or refinement as knowledge of the disease increases.

To ensure complete evaluation, inspection of the pelvis in a clockwise or counterclockwise fashion is encouraged. Number, size and location of endometrial implants, plaques, endometriomas and/or adhesions are noted. For example, five separate 0.5cm superficial implants on the peritoneum (2.5 cm total) would be assigned 2 points. (The surface of the uterus should be considered peritoneum.) The severity of the endometriosis or adhesions should be assigned the highest score only for peritoneum, ovary, tube or culdesac. For example, a 4cm superficial and a 2cm deep implant of the peritoneum should be given a score of 6 (not 8). A 4cm deep endometrioma of the ovary associated with more than 3cm of superficial disease should be scored 20 (not 24).

In those patients with only one adenexa, points applied to disease of the remaining tube and ovary should be multipled by two. **Points assigned may be circled and totaled. Aggregation of points indicates stage of disease (minimal, mild, moderate, or severe).

The presence of endometriosis of the bowel, urinary tract, fallopian tube, vagina, cervix, skin etc., should be documented under "additional endometriosis." Other pathology such as tubal occlusion, leiomyomata, uterine anomaly, etc., should be documented under "associated pathology." All pathology should be depicted as specifically as possible on the sketch of pelvic organs, and means of observation (laparoscopy or laparotomy) should be noted.

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HYSTEROSCOPY, UTERINE FACTORS

The uterine factors in infertility are not precisely understood at this time. It is clear that pregnancy can occur and indeed proceed to term in the face of uterine anomalies, endometrial scarring and fibroids, including the submucous variety. Nonetheless each of these conditions, as well as others such as retained IUDs, fetal bones and endometrial mucosal disturbances such as hyperplasia and polyps, clearly are related to reproductive failure even though the impact in a specific case may be relatively unpredictable.

The role of the hysteroscope is to provide direct visual appraisal of the uterine cavity in order to screen and evaluate for these conditions. The hysteroscopy should be complementary to the hysterosalpingogram. However, the introduction of hysteroscopy has in many cases supplanted the curettage in uterine appraisal. Hysteroscopy will provide the same or better information about uterine cavity contour and contents without the trauma of blind curettage. Endometrial sampling by biopsy can be done concomitant with the hysteroscopy and confirmation of any abnormalities visualized can be done with a blunt curette, if necessary.

Appraisal of the cervix during hysteroscopy is also important. Cervical incompetence is often associated with loss of the internal cervical os, producing a funnel shaped cavity whose apex is the external os. Although biochemical changes in cervical collagen may be responsible for some cases of recurrent abortion, architectural changes may be seen and suggest performance of a circlage procedure in the next pregnancy.

Although the presence of a uterine septum, submucous fibroid, or intrauterine scars does not guarantee reproductive failure, clinical experience supports therapeutic intervention when recurrent abortion and/or infertility coexist with these conditions. Indeed many would agree that submucous myomectomy is appropriate in any affected woman planning a pregnancy to avoid the risk of an incomplete abortion which cannot be satisfactorily curetted and lead to an infection of the retained tissue.

The hysteroscope has been successfully used to repair the septate uterus, varying degrees of Asherman's syndrome, cervical stenosis, and to remove embedded intrauterine devices and retained fetal bone. The hysteroscope has also been used in experimental studies to treat submucous fibroids by partial or total resection. Successful pregnancies have followed this hysteroscopic surgery. The advantage has been shorter hospitalization, rapid return to activities, and anatomic results in the uterine cavity comparable to transperitoneal hysterotomy techniques. A further advantage is the fact that the fundal myometrium is left intact and therefore is less likely to rupture in labor. Clearly hysteroscopic surgery of this type is very skill-dependent and should only be performed after extensive experience with hysteroscopy, and usually under laparoscopic control.

Hysterosalpingography is complementary to hysteroscopy, and provides the physician with a more complete understanding of the upper genital tract.

EVALUATION OF CERVICAL FACTOR

Physiologic Considerations

The uterine cervix and its secretion play a unique role in the process of reproduction. Cervical mucus is a complex secretion produced constantly by the secretory cells of the endocervix. A small amount of endometrial, tubal, and possibly follicular fluid may also contribute to the cervical mucus pool. Cervical mucus contains 92% to 98% water. The principle constituent of cervical secretion is a carbohydrate-rich glycoprotein of the mucin type. Other constituents include carbohydrates, serum-type proteins, lipids, enzymes, amino acids, and inorganic salts.

Secretion of cervical mucus is regulated by the ovarian hormones; estrogen stimulates the production of mucus, while progesterone inhibits and alters the secretory activity of cervical epithelial cells. Cervical mucus and many of its constituents undergo cyclic changes. At midcycle, near the time of ovulation, cervical mucus becomes more profuse, watery, alkaline and acellular. It also exhibits a good spinnbarkeit or stretchability. Mucus collected near the time of ovulation and dried on a glass slide reveals a characteristic crystallization pattern or ferning on microscopic examination. Progestational agents and pregnancy changes prevent ferning and abolish spinnbarkeit (3, 4).

ovulation time, allows the entry of sperm into the uterus, and at other times bars their admission.

From a functional point of view, the following properties may be ascribed to the cervix and its secretion: (a) receptivity to sperm penetration at or near ovulation, and interference with entry at other times, (b) protection of sperm from the hostile environment of the vagina and from being phagocytized, (c) supplementing the energy requirement of sperm, (d) filtering effect, (e) a sperm reservoir, and (f) a site for sperm capacitation. Current data indicate that ejaculated spermatozoa rapidly enter midcycle cervical mucus. The mucus is a favorable medium for sperm survival, and probably provides sperm with sources of energy. Retention of sperm in the mucus also protects them from the phagocytes within the female tract. There is considerable evidence that following coitus spermatozoa are stored in cervical crypts and are supplied slowly to the upper reproductive tract for several days (3).

Investigation of Cervical Factor in Infertility

Evaluation of sperm-cervical mucus interaction must be included as an integral part of infertility investigation. A stepwise plan for the evaluation of the cervical factor in infertility is shown in Figure 1. Semen analysis and examination of cervical mucus should precede postcoital tests and more specific in vitro studies.

The condition of cervical mucus greatly influences sperm receptivity; therefore, it should be evaluated accurately before a postcoital test is performed. Preovulatory mucus receptive to sperm penetration is profuse, thin, and alkaline. It exhibits intense (4+) ferning and high spinnbarkeit. A scoring system has been devised to evaluate the quality and adequacy of cervical mucus Figure 2 (1).

Several techniques for collection of cervical mucus have been described. Methods most commonly used consist of aspiration with a tuberculin or mucus syringe (without needle), pipette, polyethylene tube or sampling with mucus forceps. Cervical mucus should be collected and studied as close to the time of ovulation as possible. Clinical examination of cervical mucus includes determination of amount, viscosity, cellularity, pH, ferning, spinnbarkeit, and cultural studies, if infection is suspected. Ferning is performed by spreading cervical mucus on a glass slide and allowing it to dry. It is customarily graded from 0 to 4+, depending on the extent of crystal formation (1, 3). Spinnbarkeit is measured by placing an adequate amount of cervical mucus on a microscope slide, covering it with a coverslip, and drawing the mucus between slide and coverslip. An estimate of spinnbarkeit (in centimeters) is made by measuring the length of the thread before it breaks (1, 3). The pH of cervical mucus should be measured in situ or immediately following collection. Care should be taken to assay the pH of endocervical mucus correctly since the pH of the exocervical pool is always lower than that of the endocervical canal.

POSTCOITAL TEST (SIMS-HUHNER TEST)

Timing

Postcoital tests should be performed as closely as possible to the time of ovulation, as determined by usual clinical means (basal body temperature, cervical mucus changes, and hormonal studies). Each couple is instructed to abstain from sexual intercourse for two days prior to the test, which is performed approximately 6-10 hours after intercourse (standard test). If the initial test result is satisfactory, the test may be repeated at a longer interval of 18-24 hours (delayed test) when infertility persists. The presence in the endocervix of an adequate number of motile spermatozoa at this stage suggests favorable mucus and adequate survival of sperm in the cervix and excludes cervical factors as a cause of infertility. When the initial test yields poor results, the second test is planned 1-3 hours after coitus (early test) (3, 6).

Techniques of Postcoital Test

A nonlubricated speculum is inserted into the vagina and, using different syringes, a sample of the posterior vaginal fornix pool, exocervical and endocervical mucus is aspirated. These are placed on separate glass slides, covered with a coverslip, and examined under a microscope of 200X and 400X. If exocervical mucus is covered with cells, debris, and vaginal content, the area should be wiped dry with cotton prior to obtaining the endocervical specimen. Whenever possible, the quality of the mucus should be evaluated immediately after collection.

Interpretation

Interpreting the postcoital test requires an understanding of cervical function and sperm transport. The purpose of a postcoital test is not only to determine whether there is a sufficient number of active spermatozoa in the cervical mucus, but also to evaluate sperm survival and behavior many hours after coitus (reservoir role). Therefore, 6-10 hours after coitus is a balanced time to determine both sperm density and longevity. Earlier timing may be reserved for subjects who have negative or abnormal tests. With these facts in mind, postcoital tests may be interpreted on a rational basis, as follows:

1. Vaginal pool sample: Spermatozoa are usually destroyed in the vagina within 2-4 hours and lose their fertilizing ability within a few hours (1, 3). The purpose of examining the vaginal pool sample, therefore, is to ensure that semen have actually been deposited in the vagina.

2. Exocervical sample: the number of sperm in the lower part of the cervical canal varies with time elapsed after coitus. Within 2-3 hours after intercourse there is a large accumulation of sperm in the lower part of the cervical canal. In a normal woman, following coitus with a fertile man, more than 25 motile sperm (with 2 to 3+ motility) per high-power field (400X) are commonly observed in the exocervical specimen; 10 or more sperm per high-power field with score of 3+ motility is considered satisfactory. Less than 5 sperm per high-power field, particularly when associated with sluggish or circular motion, is an indication of oligoasthenospermia or abnormality of cervical mucus.

Sperm motility in cervical mucus is graded from 0 to 3, as follows: 0-immotile; 1-in situ motility; 2-sluggish motility; and 3-vigorous forward motility.

3. Endocervical sample: Sperm reach the level of the internal os rapidly after ejaculation. Their number increases gradually and reaches a peak approximately 2-3 hours later. Thereafter, their number remains relatively constant for up to 24 hours. At 6-10 hours after intercourse, more than 10 sperm with adequate motility (score of 3+) should normally be found per high-power field. A similar number of sperm is usually detected on a delayed test (13-24 hours after coitus).

One negative postcoital test has little clinical value and must be repeated. Persistently negative postcoital tests indicate either an abnormality of the mucus or oligoasthenospermia (2, 3, 6).

The most common cause of a negative or abnormal postcoital test is inappropriate timing. Tests performed too early or too late in the cycle may be negative in an otherwise fertile woman. In some women the test may be positive on only one or two days in the entire menstrual cycle. When ovulation cannot be timed with a reasonable degree of accuracy, serial postcoital tests should be performed.

IN VITRO STUDIES

Negative or abnormal postcoital test results are indications for in vitro cervical mucus-sperm penetration tests (1). A good correlation has been found between the results obtained by these techniques. The results of in vitro sperm-cervical mucus penetration tests also compare fairly well with sperm concentration, motility, and percent morphology in semen samples (2, 3). Finally, there is a significant correlation among the results of postcoital tests, in vitro tests, and semen analysis findings (1, 3).

Two different techniques that have been used for in vitro investigation of sperm penetration of cervical mucus are (a) the capillary tube test and (b) the slide test.

Capillary tube test

For this test, cervical mucus is aspirated into a flat capillary tube, making sure there are no air bubbles. One end of the tube is sealed with plasticine or modeling clay. The open end of the capillary tube is then placed into a reservoir containing freshly collected semen. Sperm penetration in the capillary tube is assessed at 10 minutes, 30 minutes, 3 hours, or other intervals, depending on the type of study. Both linear penetration and density of penetration are recorded. A scoring system for the evaluation of sperm penetrability has been devised (1, 3).

Slide technique

This method consists of placing a small amount of cervical mucus, stretched along the line of its strands, adjacent to a small amount of semen and bringing the two specimens into contact with each other by applying a coverslip gently over them. Care should be taken when placing the coverslip to avoid complete overlapping of the two specimens. At the interface, fingerlike projections or phalanges of seminal fluid develop within a few minutes and penetrate into the mucus. Spermatozoa usually fill these canals before entering the mucus.

In interpreting the tests, the number of spermatozoa/HPF from the interface are counted. Only those spermatozoa which are clearly within the substance of cervical mucus must be considered as having penetrated. To quantitate the test, the first microscopic field from the interface, called F1, is counted at various time intervals. The suggested times are 5 and 15 minutes after the initiation of the test. This is scored at 200X and 400X magnification. In order to study the depth of penetration, the second microscopic field adjacent to the first one, i.e., F2, and third (F3) can also be evaluated and the number of spermatozoa in these fields can be counted and recorded (1).

Crossmatch or cross-hostility tests

When both in vivo and in vitro tests are negative, normal donor sperm may be tested in vitro against the woman's cervical mucus, and preovulatory mucus obtained from a fertile donor should be tested with the man's sperm. This crossmatch test will determine whether the sperm or the cervical mucus is responsible for abnormal results.

USE OF BOVINE ESTRUS CERVICAL MUCUS FOR IN VITRO TESTS

Recently it has been shown that bovine estrus cervical mucus may be used as a substitute for human midcycle mucus (5). Bovine estrus cervical mucus is biochemically and functionally similar to human mucus. Human spermatozoa can enter bovine cervical mucus (BCM) readily in vitro and maintain good motility and viability for several hours. BCM may be used as a substitute for HCM to test in vitro sperm-cervical mucus interaction whenever difficulties are experienced in securing a sufficient amount of human material. Commercially prepared capillary tubes containing standardized samples of bovine mucus have now become available.* The use of BCM can considerably facilitate testing of the ability of spermatozoa from a given man to penetrate normal cervical mucus and will provide a new means to evaluate the etiology of an abnormal sperm-cervical mucus interaction.

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*PeneTrak Kit, Syva Corporation, Palo Alto, California

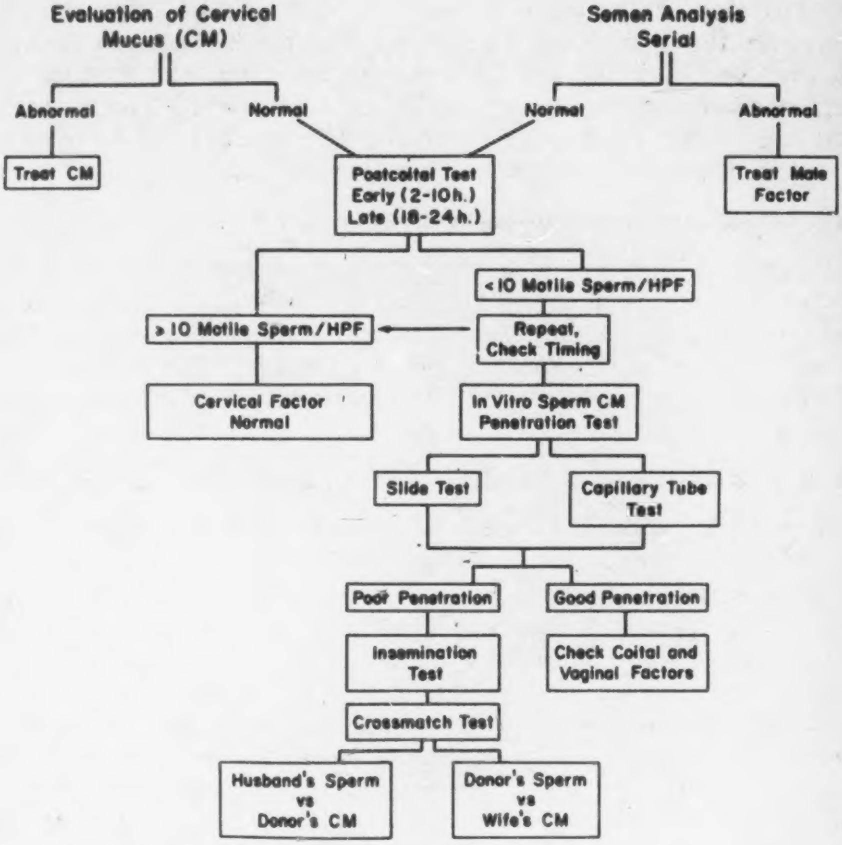
Evaluation of Cervical Mucus (CM)
Semen Analysis Serial
Abnormal
Normal
Normal
Abnormal
Treat CM
Postcoital Test Early (2-10h.) Late (18-24h.)
Treat Male Factor
<10 Motile Sperm/HPF
≥10 Motile Sperm/HPF
Repeat, Check Timing
Cervical Factor Normal
In Vitro Sperm CM Penetration Test
Slide Test
Capillary Tube Test
Poor Penetration
Good Penetration
Insemination Test
Check Coital and Vaginal Factors
Crossmatch Test
Husband's Sperm vs Donor's CM
Donor's Sperm vs Wife's CM

Fig. 1. Steps in evaluation of cervical factor

CERVICAL MUCUS

Amount	0 = 0 1 = 0.1 ml 2 = 0.2 ml 3 = 0.3 ml or more	☐
Viscosity	0 = Thick, highly viscous, premenstrual mucus 1 = Intermediate type (viscous) 2 = Mildly viscous 3 = Normal mid-cycle mucus (pre-ovulatory)	☐
Ferning (or crystallization)	0 = No crystallization 1 = Atypical fern formation 2 = Primary and secondary stems 3 = Tertiary and quarternary stems	☐

Spinnbarkeit (Place the drop of cervical mucus immediately after collection on a glass slide. Touch the cervical mucus with a cover slip and lift it gently. The length of the cervical mucus thread stretched in between is measured in cm and is scored as shown).	0 = < 1 cm 1 = 1–4 cm 2 = 5–8 cm 3 = > 9 cm	☐
Cellularity (An estimate of the number of leucocytes and other cells in the cervical mucus is made at the time of post-coital test as shown).	0 = > 11 cells/HPF 1 = 6–10 cells/HPF 2 = 1–5 cells/HPF 3 = 0 cells/HPF	☐

pH of cervical mucus ☐☐
(do not include in total score)

TOTAL SCORE* ☐☐

Fig. 2 – Cervical Score. The score is a composite of individual scores for the amount, spinnbarkeit, ferning, viscosity, and cellularity of cervical mucus. Maximum score is 15; scores less than 10 represent unfavorable mucus, and less than 5, hostile cervical secretion.

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EVALUATION OF IMMUNOLOGIC FACTORS IN INFERTILITY

A relationship between immunity to sperm and infertility has been established (1-5). In sexually active females, the reproductive tract is constantly exposed to antigenic stimuli of the spermatozoa or seminal plasma. Infertility may result from the appearance of sperm antibodies in the sera or genital tract fluids of susceptible women. Males may also produce antibodies to various antigenic components of their own spermatozoa. Sperm coated with these antibodies may fail to penetrate into or migrate through cervical mucus and reach the site of fertilization. Spermatozoa exposed to antibodies may have reduced ability to penetrate egg and initiate fertilization.

Immunity to sperm is not an all-or-none phenomenon. Sperm antibodies are a relative rather than an absolute cause of infertility.

The extent to which antisperm antibodies are present in reproductive tract secretion would be expected to influence the degree of fertility impairment (1-5).

Technique of antibody detection

Exposure of the female reproductive tract to immunogenic stimuli may result in systemic or local immune responses. In the systemic circulation, sperm antibodies may be of IgG, IgA or IgM types, whereas locally synthetized antibodies are of IgG or IgA class. In the female, the presence of sperm antibodies has been demonstrated in the serum, cervical mucus and follicular fluid.

In the male, autoantibodies against the sperm may be found in the serum and seminal fluid.

Serum tests

Several procedures have been used to demonstrate the presence of sperm antibodies in the serum (1-5, 7).

1. Tests to demonstrate sperm aggultinating antibodies: These consist of gelatin agglutination test (GAT or Kibrick test), tray slide agglutination test (TSAT), Franklin-Dukes test, and similar other tests. These tests detect sperm antibodies which reside in IgG and IgM fractions and have been used extensively for routine clinical testing. False positive results due to nonspecific reactions with sex steroids (progesterone or testosterone) and by other non-immunoglobulin serum components have been reported (1, 2, 4, 7).

2. Tests demonstrating sperm immobilizing antibodies: Complement dependent sperm immobilization test (Isojima) is a reproducible test resulting from the interaction of antibody molecules with sperm antigen which activates the complement system and disrupts the permeability and integrity of the cell membrane of the sperm acrosome and midpiece. The ultimate effect on the sperm is the loss

of motility followed by cell death. Sperm immobilizing activity resides in IgG and IgM fraction of positive sera and provides a reliable method of detecting humoral antisperm activity (4, 7).

3. Immunobead binding test (IBT): This test utilizes commercially available micron-sized polyacrylamide spheres to which isotype-specific rabbit antihuman antibodies are linked. The method allows the detection of immunoglobulins on the surface of living sperm. Additionally, the region of the sperm surface to which antibodies are bound, the proportion of sperm in the ejaculate that is antibody bound, and the isotype of these antibodies can be determined (2).

4. Radiolabeled antiglobulin assays: This test detects antibodies bound to sperm using radiolabled antibodies raised against human immunoglobulins and is apparently highly specific (2, 3).

5. Other tests: include enzyme linked immunoabsorbant assay (ELISA), immunofluorescence techniques, and mixed agglutination reaction (MAR).

Cervical mucus tests

Local isoimmunity to sperm is likely to occur throughout the female reproductive tract. However, the cervix is potentially the most important and accessible site for sperm antibody detection.

Sperm antibodies may appear in cervical mucus in the absence of detectable serum levels or may be locally secreted (2, 4-6).

In practice, cervical mucus should be preferably, but not exclusively, collected at midcycle. At this time, the mucus is more abundant and successful collection is more likely. However, preovulatory dilution of cervical mucus tends to reduce the concentration of immunoglobulins.

Various techniques have been devised to prepare cervical mucus prior to sperm antibody testing. These include ultracentrifugation to separate the gel phase from the supernatant (aqueous phase), liquefaction with Bromelin, a proteolytic enzyme, and extraction with a physiological buffer followed by centrifugation to produce an antibody-containing supernatant (4).

Tests performed for sperm antibody detection in cervical mucus consist of TSAT and microimmobilization tests.

Seminal plasma tests

Sperm antibodies of IgG or IgA types may appear in seminal plasma when they are present in relatively high titer in sera.

The measurement of sperm antibodies in seminal plasma poses special problems. Locally secreted antibodies of IgA type may not be detectable by some of the tests mentioned above. Tests commonly used for this purpose are GAT, MAR, and IBT (4).

Clinical tests

1. Postcoital test (PCT): A properly performed postcoital test serves as a reasonable initial step to detect sperm antibodies either in the male or the female. When cervical mucus is of good quality and semen analysis measures are within the normal range, a negative or poor postcoital test may be indicative of the presence of sperm antibodies either in cervical mucus or semen. When sperm antibodies are present in the serum or cervical mucus of the female, postcoital test is poor or negative in 2/3 of patients and satisfactory in the remaining ones. Sperm antibodies in the sera or seminal plasma of men also affects adversely the PCT. Approximately 50% of PCTs would be expected to be poor or negative when sperm antibodies are present in the sera of male partners of infertile women (5, 6).

2. Sperm-cervical mucus penetration test

This test evaluates sperm-cervical mucus interaction under more controlled in vitro conditons. Either slide test or capillary tube test may be used. Crossmatch (cross-hostility) testing (see previous section) may provide additional information relative to the site of local antisperm activity (4, 5). It appears that the mucus penetrability of antibody-bound human sperm may not be impaired within bovine cervical mucus while these same sperm invariably fail to penetrate human cervical mucus. Thus bovine cervical mucus may not be a suitable substitute for human cervical mucus if the presence of sperm antibodies in the semen or cervical mucus are suspected (2).

3. Sperm-cervical mucus contact test (SCMC)

This test demonstrates the presence of local antibody in either partner. A positive test is characterized by shaking movements of the sperm when placed on a glass slide to contact with cervical mucus. Recent evidence suggests that the shaking phenomenon can be mediated by F(ab)2 fragments of antisperm antibodies in both IgA and IgG classes (4). This test is a valuable method for the detection of locally produced sperm antibodies, particularly in centers where direct assay for antibody testing is not available.

Incidence of sperm antibodies

The incidence of sperm antibodies varies according to the population screened and tests used. Couples with persistent or unexplained infertility are expected to have a higher incidence of positive tests. Similarly more specific tests should yield fewer false positive or negative results. Various reports have indicated that sperm antibody activities may be detected in approximately 12% of sera and 24% of cervical mucus of females and in 6% of male sera of couples with persistent and/or unexplained infertility (1-6).

Clinical significance of sperm antibodies

Immunoreaction to spermatozoa interferes with fertility in both male and female. The presence of sperm antibodies in the semen or cervical mucus bears a stronger relationship to impaired fertility than antibodies in the sera. However, spontaneous pregnancies may occur in 20 to 50% of couples who show positive tests (1-5). In patients with positive sperm antibodies who achieve pregnancy, a high incidence of spontaneous abortion has been observed (1, 2).

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EVALUATION OF THE INFERTILE MALE

Infertility, defined as an inability to produce a pregnancy within a one year period of sexual intercourse without contraceptive measures, affects approximately 15% of married couples in America today. It is estimated that in 40-50% of the cases "male factor" infertility is the cause of or contributes to the barren relationship. However, infertility should not be viewed as solely male-related or female-related, but as a relative concept involving varying degrees of fertility potential of both partners in the conjugal relationship. A male with low fertility potential may be able to produce a pregnancy if paired with a female of high potential, and vice versa. Alternatively, sterility constitutes an absolute condition, manifested by an inability to naturally conceive.

CAUSES OF MALE INFERTILITY

Male infertility may be categorized into four etiologic groups: a) Spermatogenesis Factors; b) Ductal Factors; c) Semen Factors; and d) Coital Factors. Defects in spermatogenesis may be associated with primary testicular diseases due to genetic abnormalities (e.g., Klinefelter's or Down's syndrome), non-genetic disorders of gonadal development, idiopathic tubular or interstitial testicular lesions, dysfunctions in the hypothalamic-pituitary-testicular axis, cryptorchidism, varicocele, exposure of the scrotum to elevations in temperature from an external source or to excessive vibration, autoimmune orchitis, emotional stress, certain drugs, radiation, etc. Malformations or obstructions in the transport ducts or accessory sex glands may result in oligozoospermia or azoospermia. Such problems may be congenital (e.g., absence of vas deferens or stenosis of the ejaculatory ducts), postinfectious (e.g., epididymitis or prostatitis) or postsurgical (e.g., postvasectomy). Retrograde ejaculatory disturbances may be due to diabetic neuropathy, sympathectomy, or injury to the sympathic nerves – not uncommon following retroperitoneal node dissection. Finally, the following phenomena may be considered coital factors or problems in delivery of semen into the vagina: impotence, ejaculatory incompetence, hypospadias, improper coital technique, abnormally long or short abstention intervals or the improper use of spermatocidal lubricants.

CLINICAL HISTORY

Obtaining a detailed medical history is important in the infertility evaluation. The duration of the marriage and duration of the infertility, and a history of conceptions, miscarriages and children of the current marriage, previous marriages and sexual encounters should be ascertained. Patients should be asked if problems exist with erection, intromission, ejaculation via coitus or masturbation, premature ejaculation or ejaculatory frequency. The couple should be queried as to their frequency of intercourse, if proper coital techniques are being used and if the timing of intercourse in relation to the wife's menses is correct. The nature of the man's occupation and recreational activities should be discussed for potential exposure to radiation, thermal, chemical or vibrational stresses. The man should be asked if he wears tight-fitting underwear and if he frequently takes hot baths, saunas or steambaths. The medical history should include questions about previously diagnosed venereal diseases; reproductive system or urinary tract infections, surgery or trauma; tuberculosis; mumps; endocrine diseases including diabetes mellitus; multiple sclerosis; cardiovascular disease and hypertension. Finally, the patients should be asked about their use of tobacco, alcohol and medical and nonmedical drugs.

PHYSICAL EVALUATION

The physical evaluation of the suspected infertile male includes examination for abnormal expression of secondary sex characteristics, evidence of thyroid dysfunction or genitalia abnormalities, as well as routine evaluation of blood pressure, heart and lungs. The testes should be measured for size (approximately 2.5-3.0 cm in the short axis and 4.5-5.0 cm in the long axis) and consistency (firm and without nodulation). Varicocele, the most common clinical problem identified with male factor infertility, should be evaluated with the patient standing and performing the Valsalva maneuver. Other diagnostic methods used in the detection of varicocele include Doppler stethoscopic examination, scrotal thermography, internal spermatic venography, radioisotope scanning and real time sonography. However, some clinicians believe that only patients with a painful varicocele or clinically demonstrable variococele accompanied by abnormal semen parameters should undergo corrective surgery. The patient should also be examined for scrotal scars, abnormal masses, hydrocele, hypospadia, undescended testicles; and abnormalities of the epididymides, vas deferens, prostate and seminal vesicles.

LABORATORY EVALUATIONS

I. SEMEN COLLECTION

Unfortunately, with the exception of azoospermic sterility, no laboratory test exists which definitively predicts fertility potential. The reason for this probably stems from the fact that proof of fertility depends on reproductive performances of both the male and female partner, and few, if any, investigations to date have evaluated male factor parameters among infertile couples when the female factor was thoroughly ruled out as a participating cause of the infertile relationship. Traditionally, andrologists have depended on the BASIC semen analysis which includes: semen volume, pH, color, odor, liquefaction and viscosity measurements and sperm counts, viability, motility, and morphology determinations (See BASIC Semen Analysis Report Sheet).

The foremost important aspect of an accurate semen analysis is proper specimen collection. An interval of abstinence between emissions (usually 3-5 days) allows for rejuvenation of seminal factors and provides standardization for treatment protocols and comparisons to be made between patients. Semen should be collected in a clean (preferably sterile), dry container previously tested for absence of spermicidal toxicity. The method of choice for collection is masturbation; however, nonspermicidal condoms are available (Milex Products, Chicago, IL or HDC Corporation, Mountain View, CA). Microbial, salivary and lubricating contamination should be avoided. It is important to have the entire ejaculate collected, since the first part contains primarily prostatic fluid and the highest sperm concentrations and the latter part contains mainly vesicular fluid, which accounts for most of the semen volume. Thus, it is important to note if any portion of the specimen is missed during collection or if spillage occurs. To avoid a prolonged time period between emission and analysis, collection in a special facility associated with the testing laboratory is preferred. If the specimen is to be transported, care should be taken not to subject the specimen to heat, cold or direct sunlight. For proper motility determinations and for functional analyses the specimen should be evaluated within 1 hour of emission. Due to individual fluctuations, 3-4 semen samples should be analyzed at intervals of several weeks.

II. BASIC SEMEN PARAMETERS

As semen characteristics may fluctuate between individual specimens, accepted reference values for semen parameters also vary among investigators. Andrology results should be used to attempt to determine the patients's reproductive deficiency and as a basis for recommending and monitoring therapy. Evaluation of semen color, odor and pH is primarily used to ensure the specimen has been recently collected and shows no grossly abnormal indications (e.g., red discoloration in patients with hemospermia or brown discoloration in patients with alkaptonuria; lack of characteristic pungent odor in patients with prostatic dysfunction; acidic pH in patients with seminal vesicle dysfunction or ejaculatory duct blockage). Semen volumes below 2.0cc or above 5.0cc may indicate accessory gland dysfunctions and can also affect sperm concentration. The consistency of the ejaculate is macroscopically examined, since sperm may be trapped and immobilized in a highly viscous or incompletely liquefied specimen.

Recognizing the need for sufficient numbers of sperm to initiate a pregnancy, many investigators have attempted to assign a critical or normal lower limit for sperm concentration. The reference value for this semen parameter has, over the past 50 years, varied from 60-20 million/cc. However, since a number of recent reports indicate that men with sperm counts below 10 million/cc can initiate pregnancies, this semen parameter, although still routinely determined and reported, is no longer believed to play a major *individual* role in the individual's fertility capacity. Oligozoospermia may reflect spermatogenic abnormalities due to primary testicular disease or to cytotoxic drugs, radiomimetic agents or febrile illness, or may result from frequent coitus, ductal obstruction or partial retrograde ejaculation. Polyzoospermia with hypospermia may be associated with seminal vesicle aplasia or dysfunction, ejaculatory duct blockage or loss of the latter portion of the ejaculate. (It must be kept in mind that sperm concentration, like other semen parameters, may vary tremendously within the same individual, so multiple analyses should be performed to determine an abnormal pattern.)

In a properly collected and processed specimen, progressive sperm motility over 50%, with most swimming quickly, is considered normal. The total number of motile sperm in the ejaculate can be calculated by multiplying together the semen volume, sperm concentration and percent motile sperm. This value can be useful in determining the number of "available sperm" capable of swimming through the female reproductive tract to the oocyte. Most andrology laboratories depend on an experienced technician to determine the percentage of sperm demonstrating progressive motility and characterize the quality of motility in a semi-quantitative manner (e.g., percent "quick" or "sluggish"; motility score on a scale of 1-4, etc.). Recently, semi-automated, computer-assisted methods for sperm motility analysis have been described employing either multiple exposure or time-lapse photomicrography or videomicrography. These newer methods produce not only percent motile, but can provide measurements of average swimming speed, an average progressiveness ratio (i.e., total swimming distance divided by straight-line progression), and histograms of the distribution of all the sperm analyzed according to speed or progressiveness ratio. Although the clinical usefulness of these more complete motility data has not yet been determined, this information is very helpful in research involving artificial stimulation of sperm motility.

Morphology of the sperm and round cells present in the ejaculate is another parameter covered in the BASIC semen analysis. Due to technical complications and individual specimen differences, significant variations have been reported in the percentage of "normal" forms in each ejaculate. Generally, values of over 50% abnormal forms have been associated with infertility. The predominance of one or more abnormal forms may indicate a particular problem. For example, the presence of large percentages of sperm with tapered heads, coiled tails and/or immature germ cells may be associated with microbial infections. Likewise, a concentration of leucocytes in semen over 1 million/cc may be suggestive of an inflammatory condition or, occasionally, leukemic infiltration of the prostate. Large percentages of sperm with tapered heads and/or amorphous heads and elevated numbers of immature sperm and precursor forms may reflect a varicocele or recent febrile illness.

III. SPECIAL ANDROLOGICAL ASSAYS

The following assays have been developed to delineate potential causes of diminished fertility capacity:

A. Biochemistry: Due to the secretory functions of the male accessory glands, various components of semen can be identified with individual glandular activities. When combined with clinical information and BASIC semen measurements, biochemical analysis of semen can often elucidate accessory gland dysfunctions. Measurable biochemicals contributed to the seminal plasma by the epididymis include carnitine and glycerylphosphorylcholine. Seminal vesicles provide most, if not all, of the fructose, seminal clot forming proteins, basic secretions and prostaglandins. Secretory products of the prostate include acid phosphatase, citric acid, clot liquefying agents, zinc and magnesium. Normal ranges for seminal plasma concentrations of the more commonly used markers include:

GLYCERYLPHOSPHORYLCHOLINE	0.4-2.6umole/cc
FRUCTOSE	0.7-5.0mg/cc
ACID PHOSPHATASE	90-980IU/dl
CITRIC ACID	1.8-8.4mg/cc
ZINC	90-280mg/L

Acrosin, a proteinase enzyme present in the sperm head, has been postulated to be involved in many aspects of the fertilization process, including penetration through cervical mucus, sperm capacitation, penetration of the zona pellucida, gamete fusion and chromatin decondensation during male pronuclear formation. Levels of this enzyme below the normal range (45-170mIU/10^7 sperm) have been related to infertility.

B. Bacteriology: The role of genital tract infections, excluding gonorrhea and tuberculosis, in male infertility is not well defined. The diagnosis of accessory gland infections can be based on a combination of clinical and laboratory indications:

Clinical Evaluation of Patient –
 history of recurrent urinary tract infections
 palpable abnormalities of the prostate or seminal vesicles

dysuria and frequency
Laboratory Evaluation of Semen –
leucospermia above 1 million/cc
presence of:
Neisseria gonorrhea
Chlamydia trachomatis
Ureaplasma urealyticum
presence of significant concentrations (over 10^4 bacteria/cc) of:
Streptococcus fecalis
Escherichia coli
Proteus sp.
incomplete liquefaction 20 minutes after emission
pH imbalances indicating prostate (basic) or seminal vesicle (acidic) dysfunction
low levels in seminal plasma of prostate biochemicals

C. Immunology: Antibodies to sperm antigens are detected more often and in higher concentrations in infertile men compared to their fertile counterparts. However, some controversy exists concerning the role of antisperm autoimmunity and infertility, since the correlation between the two is not perfect. Antisperm antibody assays are directed toward either circulating (serum) or local (sperm membrane) immunity. Commonly performed serum assays include Kibrick's macroagglutination test, Franklin-Duke's microagglutination test and Isojima's sperm immobilization test. As with any serologic assay the performance of these tests should include both positive and negative controls and rigorous adherence to proper quality control. Sera should be initially screened at 1/4 dilution and, if positive, retested during titration testing. Assays commonly performed to demonstrate sperm membrane-bound antibody include the Mixed Agglutination Reaction (MAR) and Immunobead Binding Test (IBT). In the MAR test, patient semen is mixed on a slide with RBCs precoated with human immunoglobulins and animal antiserum specific for human immunoglobulins (i.e., Coomb's serum). In the IBT assay, patient semen is mixed with polystyrene beads precoated with antibodies to human immunoglobulins. Adherence of the RBCs (MAR) or the beads (IBT) to the patient's motile sperm indicates the presence of membrane-bound antibody. Titers of serum antibodies below 1/4 are considered clinically significant only if membrane-bound antibody tests are positive. Patients positive for antisperm antibodies should be retested after an interval of at least 30 days to determine if the immune response is rising, falling or remaining stable. Since occasionally men with antisperm antibodies produce a pregnancy, laboratory results should be compared to functional sperm assays, such as cervical mucus and hamster ova penetration tests, to determine if the antibodies impair sperm performance.

D. Cervical Mucus-Sperm Interactions Tests: The two tests commonly performed to investigate the ability of patient's sperm to interact with cervical mucus include the Compatibility Test and the Penetration Test. These tests represent **in vitro** correlates to the post-coital Huhner test and can be used to delineate which partner is responsible for inadequate sperm penetration into and through the cervical canal. The Compatibility Test is a qualitative assay performed by direct microscopic observation of sperm and mucus. A 4-way cross-match system of testing is used. Semen from both the male patient and a fertile control donor are placed on separate microscope slides in contact with mid-cycle cervical mucus from the female patient and a fertile control donor. The penetration of sperm into the mucus interface is examined and scored microscopically at 5 and 15 minutes. Penetration of at least 25 sperm 1-2 high power fields (at 450x magnification) into the mucus after 15 minutes is considered normal. The Penetration Test yields quantitative information on the ability of the patient's sperm to penetrate into a column of mucus. Although human mucus can be used, it is often difficult to obtain and manipulate. A commercially-available kit for this test (Penetrak, Syva, Palo Alto, CA), which uses bovine cervical mucus, has demonstrated good correlation with human mucus and is very convenient to use. Bovine mucus, however, may not be an adequate substitute for human mucus in the presence of sperm antibodies. Several flat capillary tubes containing mucus are incubated in aliquots of patient and donor semen for 90 minutes. For normal specimens the vanguard sperm should penetrate at least 30mm into the mucus column, whereas, penetration of less than 20mm indicates reduced penetration potential.

E. Hamster Zona-free Egg Penetration Test: This assay reveals the ability of sperm to undergo capacitation, penetration of egg plasma membrane and nuclear decondensation. Sperm are washed free of seminal plasma and incubated in a medium which promotes capacitation. After an appropriate incubation period, 4-18 hours depending on the patient and the laboratory, motile sperm are used to inseminate hamster eggs previously enzyme-treated to remove the cumulus and zona pellucida. Following several hours of insemination the eggs are examined for sperm penetration. Sperm from a donor previously shown to exhibit normal penetration (above 15%) is always tested simultaneously with patient's sperm as a positive control. Penetration rates of 10% or less are considered abnormal. Results of this assay have correlated well with clinical fertility potential and human egg penetration performed in human **in vitro** fertilization programns.

F. Endocrinology; Since testicular production of sperm is under endocrine control, it is common to measure circulating testosterone and gonadotropin (FSH and LH) levels, and occasionally prolactin levels, in azoospermic and oligospermic males. Although male infertility may also be associated with diabetes and thyroid dysfunction, the incidence of undiagnosed cases of these disorders being a cause of infertility is very low and defects in spermatogenesis would become apparent only in advanced stages.

True endocrinologic infertility of the male, although rare, can be separated into 3 subgroups: a) hypogonadotropic hypogonadism, b) hypergonadotropic hypogonadism and c) infertility with FSH and/or LH and testosterone levels normal or slightly elevated. Primary hypogonadotropic hypogonadism occurs prior to puberty and is easily identified by history and physical exam. Patients exhibit infantile genitalia and lack of virilization. Secondary hypogonadotropic hypogonadism occurs after puberty and patients exhibit normal masculinization, but may have decreased libido and/or impotence. In either condition the endocrine laboratory evaluation reveals depressed levels of plasma testosterone, LH, and FSH and patients fail to release gonadotropins in response to stimulation by clomiphene citrate. These conditions may be selective for gonadotropins or can represent panhypopituitarism associated with short stature, adrenal and/or thyroid deficiencies. These patients should be thoroughly evaluated for hypothalamic and pituitary diseases. Response to treatment with gonadotropins (hCG-hMG) is relatively simple and, although testicular function often does not reach normal levels, enough sperm production often does result to produce pregnancies.

Hypergonadotropism may be primary (e.g., Klinefelter's syndrome, testicular atrophy due to bilateral testicular torsion, bilateral cryptorchidism) or may follow exposure to radiation or cytotoxic chemicals. No treatment is available, although spontaneous recovery may occur in cases of secondary hypergonadotropic conditions.

When FSH, LH and testosterone are within normal ranges or only slightly elevated and the patient is azoospermic or oligozoospermic, reproductive tract blockage should be ruled out by clinical evaluation, semen biochemistry, testicular biopsy and vasogram. Similarly, these patients should be evaluated for varicocele and retrograde ejaculation. Recent research investigations have hypothesized that infertile patients with normal circulating levels of gonadotropins may exhibit dysfunction of Leydig cells and/or Sertoli cells, however, the clinical usefulness of this information has not yet been determined. In these patients the particular semen abnormalities must be treated in the laboratory setting (e.g., artificial insemination with a split ejaculate or **in vitro** fertilization).

CONCLUSION

The accurate assessment of male fertility potential by clinical and laboratory parameters is difficult due to the wide ranges of normal values seen within the human population (and which often overlap abnormal values), the normal fluctuations seen within each individual, and the contribution of the female to the end-point determination of fertility (conception). Unfortunately, the problem has been exacerbated by conflicting data in the scientific literature due primarily to the lack of standardized andrological protocols. The diagnosis and treatment of infertility has historically been performed by scientists acting as dilettantes in the field of reproductive medicine. However, more recently it has become apparent that in order to properly study the infertile couple a team of scientists, properly trained in gynecology, urology and laboratory andrology, must be available. By a systematic evaluation of the medical and personal histories, physical examinations and appropriate laboratory tests, the clinician should be able to delineate the cause of the reproductive defect in the majority of infertile couples and institute corrective therapy.

SEMEN ANALYSIS REPORT: BASIC ANALYSIS

PHYSICIAN: ____________________
OFFICE: ____________________
SPECIMEN NO.: ____________________

PATIENT NAME: ________________ SPOUSE'S NAME: ________________
PATIENT S.S.#: ________________ SPOUSES S.S.#: ________________
ANDROLOGY SERVICE(S) REQUESTED: ____________________

SPECIMEN

DATA COLLECTED: _____ TIME COLLECTED: _____ TIME ARRIVED IN LAB _____

COMPLETE _____/INCOMPLETE _____ IF INCOMPLETE, PORTION LOST: _____
LOCATION OF COLLECTION: __________ DATE OF LAST EMISSION: __________

GROSS EXAMINATION		**REFERENCE VALUES**
VOLUME:	__________ ml	2.0-5.0 ml
pH:	___ (time: _____)	Alkaline
COLOR:	__________	Gray-white
LIQUEFACTION:	__________	Complete by 20 min
VISCOSITY:	__________	Completely liquid

MICROSCOPIC EXAMINATION

PARTICULATE DEBRIS: ______________________ Not excessive

AGGLUTINATED CLUMPS: ____________________ Not excessive

MUCUS: ______________________________ Not excessive

SPERM MOTILITY (time: __________) . . . . Over 50% progressive with most quick

TOTAL PROGRESSIVE: ________________%

QUICK PROGRESSIVE: ____________%

SLUGGISH PROGRESSIVE: __________%

NON-PROGRESSIVE: __________%

SPERM VIABILITY: __________ % dead . . . . . Less than 35% dead

SPERM CONCENTRATION . . . . 20-200 million/ml

1/ ________ dilution: ________ million/ml

1/ ________ dilution: ________ million/ml

TOTAL PROGRESSIVE

SPERM PER EJACULATE: ________ million . . Over 50 million

QUICK PROGRESSIVE

SPERM PER EJACULATE: ________ million . .

SPERM MORPHOLOGY . . . . Over 50% normal

NORMAL OVAL: ________%

ABNORMAL: __________%

SMALL OVAL HEADS: _______________%

AMORPHOUS HEADS: _______________%

CYTOPLAMIC DROPLETS: ___________%

DOUBLE HEADS OR TAILS: __________%

COILED TAILS: ____________________%

LARGE OVAL HEADS: _____%

NECK DEFECTS: _________%

ROUND HEADS: _________%

TAPERED HEADS: _______%

OTHER ABNORMAL FORMS: ________%:____________________________

ROUND CELLS: _________________________

WBCs: ________ %

IMMATURE GERM CELLS: ________ %

COMMENTS

AUTOMATED SEMEN ANALYSIS REPORT

AID DONOR 4340 3/27/85

FILE: 000000004340 4340 AID DONOR **3-30-85**

TECHNICIAN:

CELL CONC	MOTILITY	MOTILE MEAN VELOCITY	MOTILE MEAN PROGRESSION
137,806,700.00 PER ML	62.77%	24.12 MICRON/S (SD: 7.30) (SEM: 0.67)	8.21

TOTAL CELLS ANALYZED:	188	INDEX OF MOTILITY:	15.14
TOTAL FRAMES ANALYZED:	3	CONCENTRATION MOTILE:	86,495,690.00 PER ML

AVG. VELOCITY LINEAR (7.5-10.0)	AVG. VELOCITY NON-LINEAR (0-7.5)
23.55 MICRONS/S	26.70 MICRONS/S

VELOCITY DISTRIBUTION %

VELOCITY RANGE: (MICRONS/SECOND)	0 – 10	– 20	– 30	– 40	– 50	– 60	– 70	– 80	– 90	– 100	– 100 +
% DISTRIBUTION:	3.4	20.3	54.2	22.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
RUNNING TOTAL %:	3.4	23.7	78.0	100	100	100	100	100	100	100	100.0

PROGRESSION DISTRIBUTION % (MOVING CELLS ONLY)

PROGRESSION RANGE: (DISTANCE/LENGTH) % DISTRIBUTION	0 – 1	– 2	– 3	– 4	– 5	– 6	– 7	– 8	– 9	– 10
	0.0	0.0	1.7	0.8	1.7	1.7	9.3	21.2	21.2	41.5

EVALUATION OF COUPLES FOR IN VITRO FERTILIZATION

In vitro fertilization, with a few exceptions, remains a method of therapy for various causes of infertility only after the failure of more conventional modalities. Thus, couples will have previously had the various workups described in earlier sections of this book. However, when a decision is made to resort to in vitro fertilization, it is important that the necessary studies required prior to in vitro fertilization be contemporaneous, It is not adequate to depend on studies which are more than six to twelve months old. This is especially true for such things as sperm counts, documentation of ovulation, hysterograms, etc.

Indications for In Vitro Fertilization

In vitro fertilization was first applied to patients with uncorrectable tubal disease and these patients still represent the bulk of those treated with this method. Nevertheless, conventional in vitro fertilization may now be applied to several other situations. Among these are couples whose husbands have inadequate sperm for normal reproduction, couples whose wives have endometriosis or have had intrauterine exposure to diethylstilbestrol (DES), or have cervical secretions which are hostile to the sperm, or may have intractible anovulation. In addition, in vitro fertilization may be applied to couples where antisperm antibodies seem to be the cause of their infertility and among couples with undiagnosed infertility – the so-called "normal infertile couple."

Using a variant of the basic in vitro fertilization, the process may be applied with success where donor sperm are required, among couples whose husbands have hopelessly inadequate sperm and where the wife also has some uncorrectable abnormality which can be circumvented by in vitro fertilization.

The option also exists of using donor eggs in a situation where the husband has adequate sperm but where the female partner either has no ovaries, non-functioning ovaries, genetically defective oocytes, or ovaries which are so located that eggs cannot be harvested from them.

Requirements for In Vitro Fertilization

Most programs require that the couples be legally married. Nevertheless, some programs will accept couples who have a stable relationship.

The ovaries must be accessible. Preferably this is by laparoscopy but in the event the ovaries are not laparoscopically available, transvesicle or transvaginal ultrasound guided aspiration can be used. However, to date, it remains to be shown that the ultrasonic guided aspiration is as efficient as laparoscopic harvest.

The uterus must be functionally normal.

The menstrual function must be normal or easily correctable, i.e. oocytes must be present and recruitable.

The age of the wife is a subject of some uncertainty. Good results have been obtained through age 39. At age 40 and above the results are inferior but not completely zero. Therefore, patients age 40 and above should certainly be discouraged. However, an absolute upper age limit remains to be established. There is obviously some variation in oocycte recruitability during this premenopausal era.

Evaluation of the Wife

Ovarian availability must be determined by laparoscopy subsequent to any previous abdominal operative procedure. This may be determined by an interval diagnostic laparoscopy or can be determined at the first planned egg harvest in association with ovarian stimulation. If the former plan is adopted, the matter of ovarian availability can be determined prior to entering into an in vitro program. If the latter plan is pursued, all concerned must be prepared for disappointment in the event one or both ovaries prove not to be available.

Some individualization of advice on the best alternative is required. Information about past operative procedures and the pelvic examination can help to make the right decision.

If the ovaries prove to be partly or entirely unavailable by virtue of adhesions, good results have been obtained by a preliminary laparotomy which has as its objective the liberation of the ovaries, the removal of any residual tubes, and the suspension of the ovaries, and if necessary, the uterus.

The uterine cavity must be examined by an adequate hysterogram. It is necessary to insist on examining a film which has been taken with downward traction on the cervix to place the uterus in midposition to make it possible to have an outline of the uterine cavity in a flat anterior-posterior projection. Hysterograms taken of the uterus in the normal anterior position or in retroposition where the uterine cavity is visualized transfundally in the axis of the fundus-cervix are often not completely satisfactory for outlining the uterine cavity.

Where some abnormality in the uterine cavity is demonstrated, the identification of the abnormality by hysteroscopy is essential.

If there is any reason to be concerned about cervical competence from the history, suitable determinations to establish or rule out this condition are in order.

An entirely normal uterine cavity is desirable. However, it has been surprising that some patients whose infertility is on the basis of intrauterine exposure to DES (e.g. post-salpingectomies for ectopic pregnancies) and who have deformities of the uterine cavity due to the

DES exposure have, in fact, had successful pregnancies by virtue of in vitro fertilization. Therefore, these patients can be considered for an in vitro program if advised of the increased risks.

The demonstration of cyclic menstrual function as documented by basal temperature chart is desirable.

It is not customary in medical practice to require a patient to document the date of birth. Nevertheless, some programs of in vitro fertilization have encountered deception by an understating of the age of the woman so as not to be refused treatment. In selected cases, therefore, when there is some suspicion that the patient may be older than her stated age, it may be desirable to verify the date of birth independently.

Evaluation of the Husband

A semen examination is a basic requirement. This should be obtained under satisfactory circumstances after three days of abstinence. Any count which is in excess of 20 million per cc with 40% actively motile sperm and no more than 40% abnormal forms can be considered to be normal. If there is a deficiency in any of these parameters, verification by the examination of repeat specimens are in order and additional studies may be indicated.

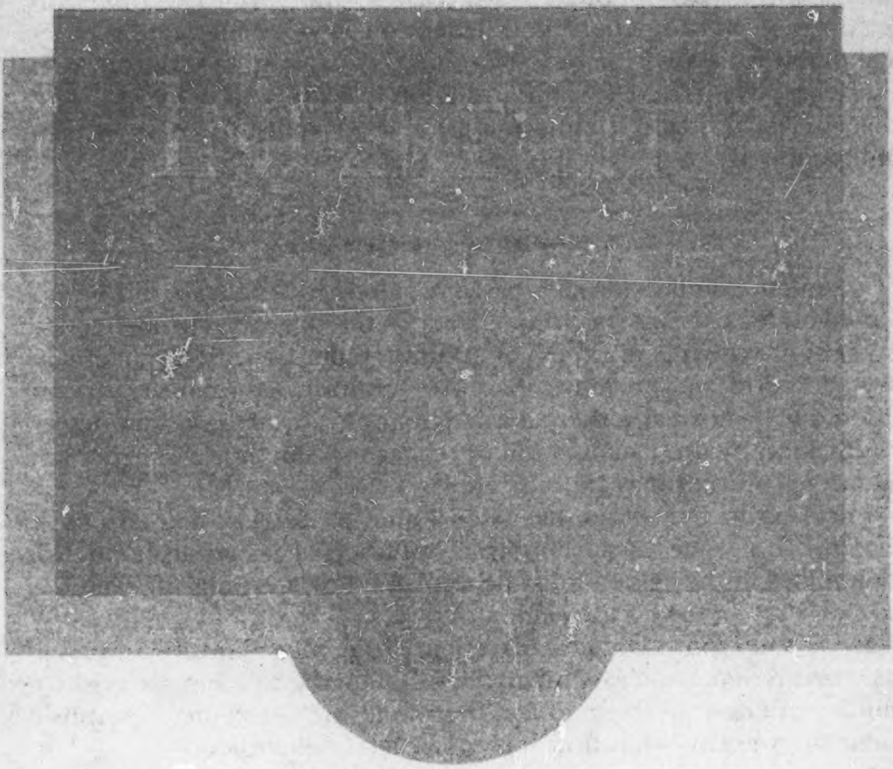
Infection in the semen has been found to be very deleterious so that the presence of an abnormal number of polymorphonuclear leukocytes in the semen must be explained by a urological examination and by culturing the semen.

It has been routine practice in some programs to culture for ureaplasm urealyticum and for chlamydia although the relation of a positive culture of either of these to fertilization in the subsequent establishment of pregnancy has not been completely elucidated.

In the event repeated examinations show some deficiency in one or another of the parameters in the semen, preparation of a semen specimen exactly as it is done for in vitro fertilization is desirable to assure that it will be possible to have an adequate number of actively motile sperm for fertilization in vitro. This includes a "swim-up" procedure, and a minimum of 100,000 available actively motile sperm is a minimum requirement for success.

The hamster penetration test is proving to be a reliable index of the fertilizing capacity of the sperm in vitro although it is not without exceptions. Nevertheless, a useful guide to the probability of fertilization in vitro can be obtained from running this test and in many programs this is required in the oligospermic group.

THE AMERICAN FERTILITY SOCIETY



PATIENT INFORMATION SERIES

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THE AMERICAN FERTILITY SOCIETY

INFERTILITY

An Overview

INFERTILITY IN PERSPECTIVE

If you and your partner have failed to achieve a pregnancy within one year of unprotected intercourse, you're not alone. Almost 2.4 million American couples, or 15 percent, have the same problem. In fact, the first-time pregnancy rate for all couples is only 80 percent within the first year of trying. Frustration, jealousy, guilt, and anger often grip the infertile couple. But help is available.

Dramatic advances based on fertility research have been made in recent years, and more are expected. Breakthroughs in medication, microsurgery, and in vitro fertilization techniques offer more hope than ever before. In most cases today experts can identify the factors that reduce fertility, and many of those factors are treatable. Pregnancy is possible for more than half of the couples pursuing treatment.

Finding a physician who specializes in infertility management is an excellent first step. He or she will perform a thorough investigation to determine why you haven't conceived and what to do about it. You and your partner will be asked to undergo a series of tests that require a joint investment of time, money, and physical and emotional energy.

Evaluation and treatment, of course, does not guarantee success. Not every couple can conceive, but you and your partner may gain a better understanding of why you are infertile. This pamphlet reviews an approach to the evaluation and treatment of infertility that many specialists follow, at least in part.

THE INITIAL VISIT

Because the factors that reduce fertility are shared almost equally by the male and female, both partners must be evaluated. Your physician will ask a lot of questions while compiling a thorough history of each partner and will review any records you may have from a previous infertility evaluation. You and your partner should plan to attend the first meeting together. During this visit, you'll begin to understand the degree of commitment and cooperation this investigation requires.

In a typical interview, the specialist asks the woman if she has irregular periods, severe menstrual cramps, pelvic pain, abnormal vaginal bleeding or discharge, genital infections, or any medical illnesses. The physician will also ask about any prior miscarriages, pregnancies, surgery, and methods of contraception.

The man answers questions covering genital injury, surgery, infection, drug and/or medication usage, and medical illnesses. The physician will ask how long you've been trying to conceive, how often you have sexual intercourse, if you use lubricants during intercourse, and if anyone in your family has birth defects.

The complete sexual and reproductive histories of each partner, including former relationships, if any, must also be considered. During the first visit many specialists discuss the emotional stress of being infertile, a subject that is often difficult to share with family and friends.

The interviews are usually followed by complete physical examinations that direct special attention to the reproductive organs. Your physician will be especially alert to signs of hormone imbalance and, depending on your individual case, may schedule blood tests to measure hormone levels.

Some physicians may begin testing during the first visit, based on indications from the history and physical of each partner. For example, if the specialist suspects an infection that could impair a future pregnancy, he or she may test for it. Other tests must be performed at specific times of the menstrual cycle.

TESTING FERTILITY FACTORS

The Ovulation Factor

A woman's menstrual pattern may reveal some important clues about *ovulation*. Failure to ovulate or produce sufficient progesterone accounts for approximately 25 percent of all infertility cases. Charting your *basal body temperature* (BBT) is a simple, inexpensive tool for estimating the time of ovulation and may reflect progesterone production that follows ovulation. Progesterone is a hormone produced by the ovaries that transforms the uterine lining into a suitable bed for implantation and nurturing of the fertilized egg.

To complete a BBT chart, take your temperature orally each morning the moment you awaken, *before doing anything else*. Then plot the temperature with a dot under the appropriate date. Normally, the release of progesterone causes a mid-cycle temperature rise which indicates that ovulation occurred.

A completed chart may suggest problems such as anovulation (lack of ovulation) or inadequate progesterone production, in which case the fertilized egg may not successully implant. The BBT chart also helps in scheduling tests that must be performed at specific points in the menstrual cycle.

But remember, the BBT chart does not directly indicate ovulation or progesterone production. Many factors unrelated to the reproductive cycle, such as a cold or fatigue, can affect your basal temperature. At best, the BBT chart helps determine when and if you ovulated. Kits are available that may help predict your time of ovulation by detecting the presence of the hormone LH in the urine. LH is the hormone that stimulates the ovaries to release eggs. Your doctor may recommend this test for you.

Another common procedure, an *endometrial biopsy*, more accurately evaluates your body's production of ovarian hormones. Just before your period begins, a small piece of tissue is removed from the endometrium, the inner lining of the uterus. The tissue is then examined under a microscope to determine if the inner lining of the uterus has responded adequately to progesterone production.

The ovaries begin producing progesterone only after ovulation, and, in a normal cycle, the progesterone level peaks about seven days thereafter. For this reason, your physician must know the starting date of your next period to interpret the biopsy correctly. The appearance of the tissue may reflect adequate or inadequate hormone production. The blood level of progesterone may also be tested to determine whether ovulation has occurred or to indicate the presence or absence of a hormone problem.

The Male Factor

In approximately 40 percent of infertile couples the male factor is either the sole or a contributing cause. For this reason a *semen analysis* is very important. Usually the man is asked to collect a semen sample by masturbation. The specimen is examined under a microscope to determine the number and motility (movement) of sperm and to assess their shapes. Because the results of semen analyses for the same man can fluctuate widely from one time to another, more than one test may be necessary. Several days must pass between the tests.

Other tests may be necessary for the male, such as a *hamster egg penetration test* or blood hormone tests. In the hamster egg test, a semen sample is incubated with hamster eggs (oocytes) to see what percentage of eggs the sperm can penetrate.

The Cervical Factor

Conditions within the cervix can contribute to infertility, although somewhat less than five percent of infertility problems are traceable solely to the cervix. Your physician may recommend a *postcoital test* (PCT), which evaluates the cervical mucus, sperm, and interaction between the two. The procedure is performed during the days just before ovulation.

This is the only time in the menstrual cycle when the mucus should be clear, colorless, watery, abundant, and stretchable. These are prime conditions for sperm passage. About two to 12 hours after intercourse a sample of cervical mucus is taken during a routine pelvic exam. If the mucus is of good quality, microscopic examination should reveal healthy sperm swimming smoothly and moving forward.

When the mucus is favorable to sperm passage, a below-average number of moving sperm may indicate a problem with sperm production, delivery to the vagina, or an immunological disorder. In the latter instance, antibodies that kill the sperm are present in the cervical mucus, the seminal fluid, or both. Blood tests of both partners may be necessary to detect these antibodies.

On the other hand, if mucus quality is poor or if the quantity is inadequate, the cervix may be at fault. The most likely explanation is that the test was performed at the wrong time of the menstrual cycle. Because test timing is crucial, your physician will probably ask you to record your temperature daily and notify him or her when it rises (usually one to three days after the test). Often more than one PCT is necessary within the same menstrual cycle.

The Uterine Factor

Defects in the uterus are often detectable by a special X-ray called a *hysterosalpingogram*. This is done just after your menstrual period stops and before ovulation. Problems the X-ray may reveal include uterine scar tissue, polyps (bunched-up pieces of the lining), fibroids, or an abnormally shaped uterine cavity. These conditions, which are seen in about five percent of infertile women, can interfere with secure implantation of the fertilized egg.

The procedure involves injecting a solution visible by X-ray through the cervix. The moderate cramping that usually results can be eased with medication. As the solution travels through the uterus and tubes, X-ray's are taken that reveal the inner contour of these organs, also letting your physician see if the tubes are open.

Another procedure used to examine the uterine cavity is called *hysteroscopy*. A long, narrow "telescope" with a light source—a *hysteroscope*—is inserted through the cervix into the uterus. Beforehand, you are given either a local or general anesthetic. (You are awake with a local anesthetic and asleep with a general anesthetic.)

The Peritoneal Factor

Laparoscopy can reveal problems within the pelvic cavity such as scar tissue (adhesions) or endometriosis. It's a relatively minor operation, usually performed under general anesthesia, often in the hospital's "day surgery" unit.

The physician inserts a narrow, lighted "telescope"--a *laparoscope*—through a small incision below the navel. He or she then looks directly into the abdominal cavity and inspects the ovaries, tubes, uterus, and peritoneum (lining of the pelvis). During this procedure dye is usually injected through the cervix to determine if the pathways from the cervix through the uterus and tubes are open.

When tissue that normally lines the uterus grows outside the uterus as well, the condition is called *endometriosis*. Endometriosis tissue may grow on any of the pelvic cavity surfaces including the ovaries. This condition is found in about 35 percent of infertile women who have no other diagnosable problem. Laparoscopy is the simplest means of diagnosing the condition with certainty, although diagnosis is sometimes made during a more extensive operation which involves a larger abdominal incision.

The more extensive operation is usually done to relieve pelvic pain, remove ovarian cysts, or correct other pelvic problems.

The Tubal Factor

Because open tubes are necessary for conception, tests to determine tubal patency (openness) are important. Tubal and/or peritoneal factors account for about 25 percent of all infertility problems. If the hysterosalpingogram shows blocked tubes, scar tissue may be present. Your physician may perform laparoscopy to determine if scar tissue adhesions have formed on the outer surface of the tubes, and to what extent they interfere with tubal function.

Since technical problems with either hysterosalpingogram or laparoscopy can erroneously indicate blockage, both tests may be necessary to adequately evaluate your tubes. Some doctors feel that pregnancy may become possible if, during either procedure, a mucus/tissue plug is flushed out of the tubes after the dye is injected.

Laparoscopy is an important part of a thorough infertility investigation and should not be unnecessarily delayed, especially in older patients. In younger patients, however, the physician may postpone laparoscopy if the hysterosalpingogram shows open tubes, or if another problem is being treated. Even then, if no pregnancy occurs within about six months of treatment, laparoscopy is almost always suggested.

Unexplained Infertility and Uncommon Factors

In approximately ten percent of couples seeking pregnancy all tests are normal. In a much higher percentage only minor abnormalities are found. Many of these couples may choose to undergo more intensive testing for less common, subtle problems that involve the immune system, hormones, or infection. Your physician knows that the procedures and intimate questions involved in an infertility study are often stressful. You should feel free to make him or her aware of your concerns and frustrations at anytime.

TREATMENT

After identifying all detectable factors that may reduce fertility, your physician will propose a plan of action based on your individual needs. If you are not ovulating at all, an oral hormone medication may be prescribed. Possible therapies include clomiphene (Clomid or Serophene), dexamethasone (Decadron or Hexadrol), or bromocriptine (Parlodel). Up to 80 percent of women taking these medications begin to ovulate regularly and, if no other factors need treatment, approximately 40 percent of this group may become pregnant within the first six months. More potent fertility drugs (given by injection) may be prescribed if oral therapy fails.

Male factors may be treated by antibiotics, hormones, or surgery. Insemination with sperm from your partner or possibly a fertile donor may be considered. Cervical problems are treated with antibiotics and hormones, or by inseminations. Uterine structural problems often require surgery.

Endometriosis is treated with medication, surgery, or both. Although many tubal problems are correctable by surgery, women with severely damaged tubes are so unlikely to become pregnant that it is seldom attempted. The best hope of pregnancy for these women lies with *in vitro fertilization,* (IVF).

Fertility medications and/or inseminations have been used to treat unexplained infertility with limited success. If no pregnancy occurs within six to 12 treatment cycles, a reevaluation of factors may be in order. Each couple has a unique set of circumstances and the chances of treatment success vary widely. If treatment fails, you still have the options of continuing the same therapy, reevaluating the factors and, in most cases, in vitro fertilization or adoption.

"Test-tube baby" or in vitro fertilization programs have a ten to 25 percent success rate per attempt. The success of IVF depends on many factors, and is especially related to the woman's age and the reason for her infertility. Couples who try IVF for three treatment cycles may have up to a 50 percent chance of becoming pregnant. Other new techniques of assisted reproduction include *gamete intrafallopian transfer* (GIFT), and *donor embryo transfer*. Cryopreservation or freezing of eggs and embryos may be used with any of these techniques. Through the transfer of donor embryos, pregnancies can occur even in women who have no ovaries. Use of these sophisticated techniques requires a team approach that includes nurses, counselors, technicians, and physiologists, as well as physicians.

SUMMARY

Sometimes the factors preventing pregnancy are easy to detect and resolve. Often, however, they are difficult to identify and treat. For such couples, extensive evaluation may be required before the physician can recommend treatment. Up-to-date management of infertility, even by a specialist working with a team, is no guarantee of pregnancy. But full evaluation can usually uncover one or more factors that reduce fertility. Your physician can then give you a reasonable idea of your chances of becoming pregnant. The choice of which treatment to pursue, if any, is strictly a personal one.

A full evaluation usually begins with the simplest tests and progresses to those more complicated. Because each couple has a unique set of problems, the testing and treatment sequence must be individually tailored. Both partners must fully understand the extensive cooperation and the commitment of time and energy required. Even if pregnancy is not achieved, you can at least share the emotional satisfaction of having explored all the options. And the evaluation could save you time and money by revealing which therapies are unlikely to increase your chances of pregnancy.

GLOSSARY

Basal body temperature. Your body temperature at rest. It is taken orally each morning immediately upon awakening and recorded on a calendar chart. The readings are studied to help identify a woman's time of ovulation.

Donor embryo transfer. The transfer of a fertilized egg from a volunteer donor to an infertile recipient.

Endometrial biopsy. The extraction of a small piece of tissue from the endometrium (lining of the uterus) for microscopic examination.

Endometriosis. The presence of endometrial tissue (tissue that normally lines the uterus) in abnormal locations such as the ovaries, fallopian tubes and abdominal cavity.

Gamete intrafallopian transfer (GIFT). A method of assisted fertilization that involves surgically removing an egg from the woman's ovary, combining it with sperm, and immediately injecting the egg and sperm into the fallopian tube. Fertilization takes place inside the fallopian tube.

Hamster egg penetration test. A test to help evaluate the fertilizing ability of a man's sperm. A semen sample is incubated with hamster eggs to see what percentage of eggs the sperm can penetrate.

Hysterosalpingogram. An x-ray procedure in which a special dye is injected into the uterus to illustrate the inner contour of the uterus and degree of openness (patency) of the fallopian tubes.

Hysteroscope. A lighted scope through which a physician views the inside of the uterus during hysteroscopy.

Hysteroscopy. A diagnostic procedure in which a lighted scope (hysteroscope) is inserted through the cervix into the uterus to enable the physician to view the inside of the uterus.

In vitro fertilization (IVF or test-tube baby). A method of assisted reproduction that involves surgically removing an egg from the woman's ovary, combining it with sperm in a petri dish and, if fertilized, replacing the resulting embryo in the woman's uterus.

Laparoscope. A thin, lighted viewing instrument with a telescopic lens through which a surgeon views the exterior surfaces of a woman's reproductive organs and abdominal cavity.

Laparoscopy. A diagnostic procedure in which a surgeon inserts a laparoscope through a small incision below the navel; he or she then visually inspects the uterus, uterine ligaments, fallopian tubes, ovaries, and abdominal organs. One or two other punctures may be made through which additional instruments can be inserted and manipulated.

Ovulation. The expulsion of a ripened egg from its follicle in the outer layer of the ovary. It usually occurs on approximately day 14 of a normal 28-day cycle.

Postcoital test. The microscopic analysis of a sample of vaginal and cervical secretions that has been collected soon after sexual intercourse.

Semen analysis. The microscopic examination of the ejaculate to determine the number of sperm, their shapes, and their ability to move.

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acog technical bulletin

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INFERTILITY

It is estimated that at least 14% of American couples of reproductive age who desire pregnancy are unable to conceive within a year (1). The 1980s have seen a geometric rise in annual numbers of physician visits for the diagnosis and treatment of infertility, with over 3 million affected couples (2). Although the sequelae of sexually transmitted infections have played a role, especially in younger women, the "infertility epidemic" is predominantly a cultural phenomenon of the "baby boom" generation. The postponement of pregnancy, combined with the attempt to condense childbearing into a shorter time interval, have resulted in an increasing proportion of infertile couples seeking medical care (3). At the same time, the demand by patients for sophisticated diagnosis and treatment has been met by an increasing number of physicians providing infertility services (4).

Infertility is a condition with unique and profound psychologic and emotional impacts. Infertility is experienced by most couples as a life crisis in which they feel isolated and powerless. Feelings of frustration, anger, depression, grief, guilt, and anxiety are common and should be anticipated and dealt with appropriately.

The commitment to provide infertility care is therefore not a trivial one. It is important for health care providers to understand and accept the emotional and educational needs and demands of infertility patients. Physicians must honestly appraise their interests, personalities, training, and experience and be prepared to refer patients to others when appropriate. In addition, a team approach may be helpful in ensuring that patients receive an adequate workup and counseling as the need arises.

This bulletin is intended to provide an overview of the evaluation of the infertile couple, with an emphasis on the investigation of frequently seen disorders associated with infertility. The evaluation of specific problem areas and therapeutic modalities will be covered elsewhere (5, 6).

Evaluation

The goals of an infertility evaluation are to provide a rational, organized approach to diagnosis, to present an accurate assessment of progress and prognosis during the evaluation, and to offer emotional and psychologic support.

The organization of an infertility evaluation requires consideration of each of the factors of reproduction (male, ovulatory, pelvic, and cervical), taking into account the expense, invasiveness, and risks of each procedure and the likelihood of a significant finding. The initial assessment is followed by the basic diagnostic workup, which determines treatment and further testing options.

Initial Assessment

The initial assessment begins with an extended fertility history and physical examination. Ideally, both partners should be present at the initial interview. The couple's ages, previous pregnancies, and length of time attempting conception are important factors to be noted. A sexual history includes the frequency of intercourse, use of lubricants (which can be spermicidal), anorgasmia, impotence, and dyspareunia.

A male factor is responsible for approximately 35% of cases of infertility. History of testicular surgery or injury, genitourinary infection (including sexually transmitted infections), postpubertal mumps, genital radiation, chemotherapy, hypospadias, or retrograde ejaculation should be noted. Physical examination of the male should include careful evaluation of genitalia, assessing testicular descent, size and consistency of testes, and possible presence of varicocele or penile anomalies. Excessive exposure to heat (hot tubs, saunas), toxic chemicals, or pesticides or use of marijuana or nicotine (7) should be eliminated. Alcohol consumption should be minimized.

A pelvic factor is responsible for approximately 25% of cases of infertility and includes abnormalities of the uterus, fallopian tubes, ovaries, and adjacent pelvic structures. It is suggested by a history of pelvic infection, including salpingitis (pelvic inflammatory disease), septic abortion, ruptured appendix, use of intrauterine devices, or pelvic tuberculosis. Secondary dysmenorrhea/dyspareunia, or cyclic abdominal or pelvic pain should prompt consideration of endometriosis. A history of ectopic pregnancy, adnexal surgery, leiomyomas, or exposure to diethylstilbestrol (DES) in utero are important considerations. Physical examination may reveal pelvic tenderness, pelvic mass, uterosacral nodularity, decreased uterine mobility, or irregular uterine contour.

An ovulatory factor is responsible for approximately 20% of cases of infertility and may present as secondary amenorrhea, irregular menses (ie, chronic anovulation or oligoovulation), or luteal phase defect. Irregular cycle lengths of less than 25 days or more than 36 days or a variation of more than 7 days in consecutive cycles are suggestive of ovulation defects, especially if premenstrual molimina, amount and duration of menstrual bleeding, and dysmenorrhea are variable. Signs and symptoms of hyperthyroidism or hypothyroidism, as well as hirsutism, galactorrhea, hot flushes, weight loss (particularly if associated with endurance exercise or a history of an eating disorder), obesity, and severe psychologic stress, should be taken into consideration.

A cervical factor is responsible for approximately 10% of cases of infertility and may be suggested by a history of cone biopsy, cautery, cervicitis, obstetric trauma, or DES exposure in utero.

Following the fertility history and physical examination, the initial assessment concludes with an overview of reproductive physiology and a formulation and explanation of the basic diagnostic steps in the infertility workup. Enough time should be allowed to assess and discuss the couple's emotional response in a supportive and unhurried manner. The initiation of the basic workup need not be postponed by prolonged temperature charting or nonspecific reassurance. Most couples feel that the admonition to "relax" implies that their anxiety is responsible for their infertility—an unsupported and hurtful suggestion.

Basic Workup

The more common infertility factors can be evaluated by a minimal number of tests. These include 1) semen analysis, 2) documentation of ovulation, 3) postcoital test, and 4) evaluation of tubal patency.

A semen sample should be collected for analysis after a 48-hour abstinence period (to reflect optimal coital frequency) and evaluated within 1 hour of ejaculation. Normal values for semen parameters are shown in Table 1. If any parameters are abnormal, two additional semen analyses should be performed 2 weeks apart. If abnormalities persist, urologic consultation should be considered.

Ovulation may be assessed by three methods: basal body temperature, serum progesterone, or endometrial biopsy. Many clinicians prefer to use basal body temperature initially, rather than serum progesterone. Since progesterone is released into the circulation in a pulsatile fashion, a random progesterone level is valuable only if elevated. A low progesterone level may or may not be consistent with normal ovulation. If serum progesterone is used, levels should be measured 7 days after estimated ovulation. Laboratory values should be interpreted in light of an individual laboratory's standards. In general, values of greater than 15 ng/ml are consistent with normal ovulatory function, while levels of less than 5 ng/ml may indicate anovulation. Intermediate values may indicate a luteal phase defect and should be repeated in the following cycle for confirmation after ovulation has been detected by determination of luteinizing hormone (LH) surge in serum or urine (8). Endometrial biopsy, in addition to detecting ovulation, provides a more thorough evaluation of a luteal phase defect.

The postcoital test is an in vivo evaluation of sperm-cervical mucus interaction. The couple is asked to have intercourse after 48 hours of sexual abstinence, and the mucus is examined within 2–8 hours. The test is scheduled 24–48 hours prior to presumed ovulation in order to assess optimal mucus production. This can be most easily accomplished by the use of home test kits for detection of any increase in urinary LH or by identification of the ovulatory period by review of basal body temperature records from previous cycles as well as during the cycle in

TABLE 1. NORMAL SEMEN PARAMETERS

Determination	Normal value
Ejaculate volume	> 1 ml
Concentration	$> 20 \times 10^6$/ml
Initial progressive motility	> 50%
Normal morphology	> 60%

which the postcoital test is to be performed. For the postcoital test, mucus is removed from the endocervical canal and its quantity, clarity, pH, and spinnbarkeit are assessed. Although the evaluation of the postcoital test is subjective, the finding of 5–10 progressively motile sperm per high-power field in clear, acellular mucus with a spinnbarkeit of greater than 8 cm generally excludes a cervical factor.

Hysterosalpingography should be performed in the early proliferative phase of the cycle after the cessation of menstrual flow. Abnormal findings include congenital malformations of the uterus, submucous leiomyomas, intrauterine synechiae (Asherman syndrome), intrauterine polyps, salpingitis isthmica nodosa, tubal tuberculosis, and proximal or distal tubal block. Persistent dye collections suggestive of pelvic adhesions or hydrosalpinx may be seen on a delayed flat plate after dye instillation, the timing depending on the medium used. The procedure is contraindicated by the presence of a pelvic mass or tenderness or laboratory findings suggestive of pelvic inflammatory disease, as well as by an allergy to iodine or radiocontrast dye. Women with a history of pelvic infection are better evaluated directly by laparoscopy. The risks of hysterosalpingography include dye embolization (rare) and salpingitis (1–2%).

The results of the basic workup should be reviewed with the couple to confirm or eliminate any provisional diagnosis that may have been formulated at the initial assessment, to interpret new findings, and to discuss the options for treatment or further investigation. Frequent review sessions are essential to keep the couple informed as well as to provide emotional support and encouragement. Although couples often begin the fertility workup with hope and optimism, many find the diagnostic process itself to be stressful. Often there is ambivalence about test outcome—frustration may be felt if the results are normal, even while it is feared that poor results will mean sterility. Many couples find that participation in support groups during this time helps to alleviate feelings of isolation and provides an environment in which they can share their concerns with other infertile couples. RESOLVE, the national nonprofit infertility organization, has chapters in most areas of the country and is an excellent source of referrals for support groups and counseling.

Additional Evaluation and Management

The Male Factor

Repeated abnormality of any semen parameter may indicate the need for urologic consultation. Physical abnormalities such as hypospadias, cryptorchidism, or varicocele can be detected and genitourinary infection diagnosed and treated.

Serum testosterone, follicle-stimulating hormone (FSH), and prolactin abnormalities will identify men with germ cell aplasia, chromosomal abnormalities (such as Klinefelter syndrome), or pituitary adenomas. In cases of azospermia or severe oligospermia, the combination of testicular biopsy and semen fructose measurement will distinguish ductal obstruction from spermatogenic failure. Hypogonadotropic men may respond to treatment with human menopausal gonadotropin (hMG) or gonadotropin-releasing hormone (GnRH), whereas treatment with clomiphene, human chorionic gonadotropin (hCG), or testosterone has generally been disappointing.

Although statistics from controlled trials are lacking, surgical ligation of a varicocele, when found in association with decreased motility and increased tapering sperm forms, will result in improvement in semen parameters in most men. When the semen volume is high or a varicocele is present, the first part of the ejaculate may contain a higher motility and concentration of sperm and be used for "split-ejaculate" artificial insemination. A history of diabetes or prostatectomy may be associated with retrograde ejaculation, which may respond to ephedrine or imipramine or to artificial insemination with sperm recovered via bladder catheterization.

The sperm penetration assay, or zona-free hamster egg assay, is an attempt to test the biologic fertilizing capacity of sperm. After a 48-hour abstinence, sperm is collected, washed, preincubated, and placed in contact with 20–30 hamster eggs from which the zona pellucidas have been enzymatically removed. The incubation medium and ambient gas composition are carefully controlled to allow sperm to capacitate, undergo the acrosome reaction, and penetrate eggs. Sperm from men of proven fertility almost consistently penetrate over 10% of the eggs, while failure to penetrate at least 10% of the eggs suggests a significant male factor. The sperm penetration assay may be useful in deciding whether to perform varicocele surgery, monitoring hormonal or antibiotic treatment, screening candidates for in vitro fertilization, and evaluating unexplained infertility. Both false-positive and false-negative results may be found, and care should be taken that the results of a single assay are not overinterpreted. All 0% penetration scores should be repeated for confirmation after all possible extenuating circumstances (inadequate abstinence, improper sample collection or handling, concurrent illness or medication, or a high semen white cell count) have been eliminated (9).

The most common male factor by far is idiopathic oligospermia, for which, unfortunately, there is no effective treatment. Artificial insemination with the husband's sperm has not been shown to yield pregnancy rates greater than in untreated couples. In the presence of abnormal male factors, in vitro fertilization remains an option. The discussion of donor insemination requires sensitivity and an individualized approach but should not be delayed unnecessarily in the face of long-standing male infertility. Risk of infection, legal ramifications, adjustments of pregnancy, and effects on offspring should be thoroughly discussed with the couple and counseling offered as appropriate. The American Fertility Society has recommended the use of frozen semen since 1988.

The Pelvic Factor

Laparoscopy with chromotubation is indicated if hysterosalpingography is contraindicated or yields abnormal results or if the history or physical findings strongly suggest a pelvic factor. Laparoscopy is also indicated if other infertility factors have not been found. Management depends on the specific diagnosis.

TUBAL DISORDERS

Tubal disorders may result from prior salpingitis (pelvic inflammatory disease), endometriosis, adhesions from previous pelvic surgery, complications of intrauterine devices, previous ectopic pregnancy, tuberculous salpingitis, and salpingitis isthmica nodosa. Although lysis of mild peritubal adhesions may be accomplished under direct vision at the time of laparoscopy, many patients with tubal disease will require tuboplasty or in vitro fertilization and embryo transfer.

Tuboplasty success rates are dependent upon the degree of original inflammatory damage to the fimbriae and ciliated and secretory cells of the tube, the site of tubal closure (distal occlusion with hydrosalpinx has a poorer prognosis than does isthmic block), the causative pathogen (tuberculous salpingitis is a contraindication to tuboplasty), the postoperative length of viable tube, and the skill and experience of the surgeon. Most tubal surgery should be performed by those with specialized skills in microsurgical techniques, including use of magnification and fine suture material, atraumatic tissue handling and hemostasis, reperitonealization of raw surfaces, and adjuvant treatment to minimize adhesion formation. Pregnancy rates following tuboplasty may range from 15% or less for large hydrosalpinges to 70% or more for reversal of sterilization in which tissue trauma has been minimal. All tuboplasty patients have an increased risk of ectopic gestation.

In vitro fertilization has been successful in achieving human pregnancies since 1978. Pregnancy rates from successful in vitro fertilization programs range from 10–25% per cycle, with a 25–35% pregnancy loss rate. In vitro fertilization may be repeated several times, although it is a psychologically stressful procedure.

UTERINE DISORDERS

DES syndrome results from in utero exposure to DES, which was given to pregnant women in the 1950s and 1960s. It is marked by characteristic changes in the vagina (adenosis), cervix (ectropion, "hood," "coxcomb"), and uterus (T shaped, hypoplastic cavity). An increased incidence of infertility, spontaneous abortion, and premature labor has been associated with DES syndrome (10). There is no specific treatment.

Intrauterine synechiae (Asherman syndrome) are adhesions formed as a result of surgical instrumentation of the uterus complicated by endometritis. They are most often associated with curettage following term pregnancy, spontaneous or therapeutic abortion, or myomectomy and may present as amenorrhea, hypomenorrhea, infertility, or habitual abortion. The true incidence of Asherman syndrome is not known, but this condition probably accounts for only a small percentage of patients with secondary amenorrhea (11). The appearance of filling defects on hysterosalpingography is diagnostic. Treatment is by hysteroscopically guided lysis of adhesions. Broad-spectrum antibiotics are given orally for 14 days, and a high-dose estrogen is given orally for 2 months to stimulate endometrial proliferation. Treated patients have an increased risk of spontaneous abortion, placenta previa or accreta, and abruptio placentae, although pregnancy rates as high as 70% may be achieved.

Submucous or large intramural myomas may cause infertility or repeated abortion. Congenital anomalies and leiomyomas are associated with habitual abortion but are less commonly a cause of infertility. They should be surgically treated only if the remainder of the evaluation is negative.

ENDOMETRIOSIS

Women with endometriosis are twice as likely to be infertile as women without this condition, an increase that is without complete explanation. Endometriosis is confirmed and classified by diagnostic laparoscopy. A uniform system of classification that takes into account the presence, location, and quality of adhesions, endometriomas, and tubal distortion has been formulated by the American Fertility Society and classifies the disease as minimal, mild, moderate, and severe (stages I–IV) (12).

Treatment of endometriosis may be surgical or hormonal and is based on a confirmed laparoscopic diagnosis, the patient's age, and the extent, location, and severity of the disease. Initial treatment can often be accomplished at the time of diagnostic laparoscopy with appropriate planning and expertise. The use of conventional electrocoagulation and laser technology aids in the aggressive laparoscopic treatment of minimal, mild, and moderate stages of endometriosis. Conservative surgery has the objective of restoring normal anatomic relationships while excising or fulgurating as much damaged tissue as possible. It should be reserved for more advanced stages of endometriosis (moderate to severe). Pregnancy rates vary inversely with the severity of the endometriosis, with rates of 60% following surgery for mild to moderate disease and 35% for severe disease. Most pregnancies occur in the first year after surgery.

Medical treatment for endometriosis may involve the use of danazol, which has a direct androgenic effect. This effect leads to the atrophy of endometrial implants and produces an anovulatory, hypoestrogenic state. Side effects are common and are related to both its androgenic properties and the hypoestrogenic environment it creates. Treatment is usually for 6 months, and pregnancy rates after treatment are approximately 45%. Oral contraceptives and progestogens alone may also be used as an alternative to danazol when the latter is not well tolerated.

GnRH analogs are long-acting agonists of GnRH that, when administered daily, impede pituitary gonadotropin release, causing ovarian estrogen secretion to fall to castrate levels. Although clinically available, GnRH analogs have not been approved for this usage. The risk and significance of associated osteopenia is currently under investigation.

The Ovulatory Factor

Adrenal and thyroid disorders should be excluded by history and physical examination. Determinations of serum concentrations of FSH, or LH and FSH, are needed to exclude ovarian failure. The appropriate treatment of the anovulatory patient can then be decided on the basis of serum prolactin levels and the results of a progesterone challenge. Hyperprolactinemia causes approximately 15% of ovulation disturbances and is associated with a clinical spectrum ranging from amenorrhea with galactorrhea to subtle luteal phase defects. An elevated prolactin measurement requires consideration and exclusion of primary hypothyroidism by measurement of thyroid-stimulating hormone (TSH) levels, drug-induced dopamine depletion (antihypertensives, psychoactive medication), and pituitary tumor. Diagnostic imaging should be performed to exclude a macroadenoma. Treatment may then proceed with bromocriptine mesylate (Parlodel), with the dose titrated to return serum prolactin levels to normal. Bromocriptine has side effects (nausea, headaches, orthostatic hypotension, nasal stuffiness) that are most prominent at the institution of therapy and that can be minimized by gradual increases in dosage (13).

Women with normal prolactin levels who bleed in response to a progesterone challenge (progesterone-in-oil, 100 mg intramuscularly; or medroxyprogesterone acetate, 10 mg daily for 7–10 days) are candidates for clomiphene treatment, as are women with irregular menses or confirmed midluteal serum progesterone levels of less than 15 ng/ml (14). Clomiphene citrate is administered at 50 mg for 5 days starting on day 3–5 after menstrual or withdrawal bleeding. The response of the patient may be monitored by basal body temperature recording or midluteal phase progesterone levels or both. If ovulation does not occur or the serum progesterone level in the midluteal phase remains less than 15 ng/ml, the dose is increased to 100 mg and the treatment repeated. If dysfunction persists after the daily dose has been increased to 150 mg, dehydroepiandrosterone sulfate levels should be measured and, if elevated, treated with a glucocorticoid (eg, dexamethasone, 0.5 mg per day; or prednisone, 5 mg per day) while clomiphene is restarted at 100 mg. Some patients who fail to ovulate may respond to clomiphene at higher doses (up to 250 mg per day) or a combination of clomiphene citrate followed by hMG. Moreover, some patients who develop follicle growth on clomiphene but do not ovulate may do so after intramuscular administration of hCG, 10,000 IU, when follicle diameter as determined by ultrasound is 20 mm or greater. If clomiphene is successful in inducing ovulation, intercourse can be timed by follicle measurements with ultrasound, urinary LH kits, or every other day beginning 5–7 days after the course of clomiphene is completed. If treatment is unsuccessful, a postcoital test is useful in evaluating mucus quality.

Clomiphene successfully induces ovulation in 70% of patients, although the pregnancy rate is only 40%. The incidence of twins is increased to 5–10%. Side effects of clomiphene include hot flushes, visual disturbances, headaches, abdominal bloating, nausea, and mood alterations. Ovarian enlargement may result from multiple follicle stimulation. Patients should be monitored with pelvic examinations in order to avoid administration of clomiphene to a patient with an enlarged ovary. There is no increased incidence of spontaneous abortion or congenital malformations with clomiphene therapy.

hMG is available as an equal combination of LH and FSH (Pergonal) or as FSH alone (Metrodin). These products are used to treat women who either do not bleed when challenged with progesterone or do not ovulate in response to clomiphene. Safe and effective treatment requires rapid serum estradiol measurements in conjunction with ultrasonic monitoring of the number and diameter of ovarian follicles. Pregnancy rates of 60-80% may be achieved in patients with hypogonadotropic hypogonadism, but success rates are significantly lower in patients with polycystic ovarian syndrome. Pregnancy rates are also affected by age and the number of ovulatory cycles completed; most pregnancies are achieved within six cycles. Because of its risks (elevated rates of multiple gestation, approximately 10-15%; hyperstimulation syndrome, 1%) and expense, hMG therapy should be selectively administered.

GnRH may be administered in a pulsatile manner by a portable infusion pump to successfully treat women with hypogonadotropic hypogonadism. Most women will respond to pulses of GnRH, 50-75 ng/kg given every 60-90 minutes for 10-20 days. The intravenous route of administration has been more successful than the more convenient subcutaneous route. Treatment costs are high, but lower than those of hMG therapy.

"Luteal phase defect" is a term applied to a poorly understood group of subtle hormonal alterations clinically linked with infertility and habitual abortion. The diagnosis is suggested by an elevation in basal body temperature lasting 10 days or less (short luteal phase) or an endometrial biopsy that is histologically more than 2 days out of phase. Luteal phase defects are known to occur sporadically in many women and should be documented in two successive cycles for diagnostic validity. Once hyperprolactinemia has been excluded, treatment options include clomiphene, clomiphene plus hCG, or progesterone suppositories (25 mg twice daily during the luteal phase).

The Cervical Factor

Few or absent sperm in the presence of good-quality mucus requires a reevaluation of the male factor. If a prior semen analysis was normal, faulty coital technique (including the use of spermicidal lubricants), low or high semen volume, semen liquefaction defects, or unexpected variations in sperm count should be suspected.

Poor-quality mucus is usually thick and tenacious with poor spinnbarkeit. Inaccurate timing relative to ovulation must be excluded. A scoring system has been devised and may be used to assess the quality of cervical mucus at the time of postcoital testing (15). If many leukocytes are present, cervicitis should be suspected; cultures for bacteria, *Ureaplasma urealyticum*, and chlamydia are useful in ensuring appropriate treatment.

Absent or low quantity of mucus may reflect inaccurate timing or cervical trauma, surgery, or DES syndrome. Treatment includes low-dose oral estrogen for 1 week prior to ovulation or intrauterine insemination with washed and incubated sperm.

The presence of nonmotile or nonprogressively motile sperm with a "shaking" pattern suggests the presence of sperm antibodies in either partner. Treatment options have not been extensively evaluated but include steroid suppression and intrauterine insemination.

Unexplained Infertility

In 5-10% of couples, completion of the basic workup will not reveal any abnormalities. The evaluation should be reviewed with the couple, and measurement of serum prolactin and androgens, cervical cultures for *U. urealyticum* and chlamydia, sperm antibody testing, and a sperm penetration assay should be considered. If laparoscopy has not been done, it should be performed. Since subtle anomalies of ovulation are occasionally associated with unexplained infertility, careful scrutiny of the ovulatory process is important to correct any abnormality. There is no rational therapy for unexplained infertility, yet the couple will often request empirical treatment. Referral to a specialist may be appropriate, with ultimate consideration of the use of new reproductive technologies, such as in vitro fertilization, gamete intrafallopian transfer, or ovum transfer (6). Discussion of adoption and other alternatives may be explored with the couple and emotional support continued.

Summary

Once a couple seeks medical help for infertility, their anxiety can be allayed only by prompt and accurate diagnosis, treatment, and education given in a setting of care and understanding. The initial assessment and basic workup can be completed in a single cycle if desired and will be diagnostic in the majority of couples. There are few couples in whom diagnosis and treatment, no matter how exhaustive, cannot be completed within 12-18 months if the physician is both organized and committed and the couple is kept well informed. Physicians must recognize and carefully weigh the expense and yield of each procedure individually if limited resources are to be optimally utilized.

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This Technical Bulletin was developed under the direction of the Committee on Technical Bulletins of the American College of Obstetricians and Gynecologists. The committee wishes to thank Robert D. Nachtigall, MD, for his assistance in preparing this Technical Bulletin. Methods and techniques of clinical practice that are currently acceptable and used by recognized authorities are described in this bulletin. The recommendations in this Technical Bulletin do not dictate an exclusive course of treatment or procedure to be followed and should not be construed as excluding other acceptable methods of practice. Variations taking into account the needs of the individual patient, resources, and limitations unique to the institution or type of practice may be appropriate.

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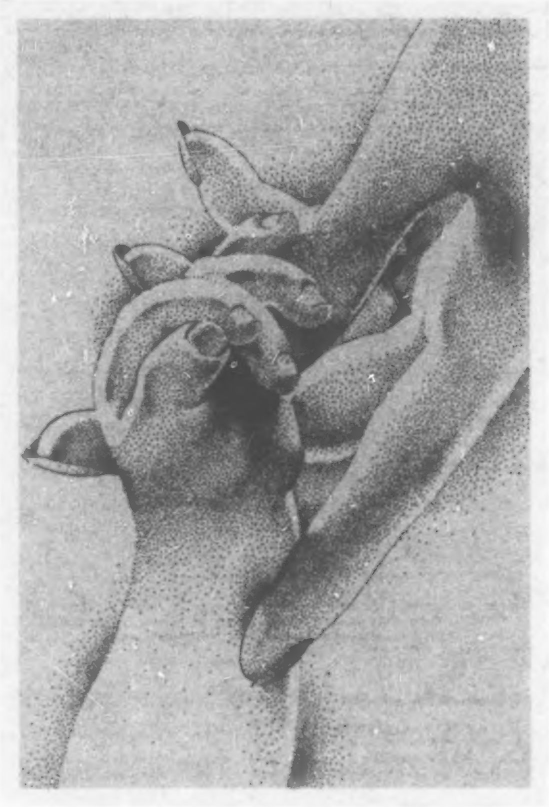
In Vitro Fertilization And Embryo Replacement



Richard P. Marrs, M.D. and
Serono Symposia, USA

In Vitro Fertilization, or IVF, is a remarkable procedure that has brought infertile couples the miracle and joy of childbirth. People who previously would have had no chance to conceive now have the chance to bear a child.

In this pamphlet, you will learn about In Vitro Fertilization, how it works, and what you need to do to investigate it further. It should give you a good general overview.

It was written by Richard P. Marrs, M.D., one of the country's most successful IVF practitioners. Dr. Marrs is presently Director, Institute of Reproductive Medicine, located at the Hospital of the Good Samaritan, Los Angeles, California.

The pamphlet was produced by Serono Symposia, USA, a division of Serono Laboratories, Inc.

Read this over. Take notes if you need to. But, most important of all, we encourage you to discuss any questions you may have with your physician.

At Serono Symposia, USA, we're committed to physician and patient education. This pamphlet is brought to you with our wishes that you find it helpful.

Sincerely,

Leslie Nies

Leslie Nies
Vice President
Medical and Consumer Affairs

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What You Should Know About The Program

You are being considered or have been selected as a candidate for an In Vitro Fertilization and Embryo Replacement (IVF-ER) Program.

The criteria for consideration or selection are based on your age, medical history, previous pregnancies, general health, and the ability of you and your husband to produce gametes (egg and sperm) that may be used for fertilization outside of your body.

The program is physically and emotionally demanding. It is also quite complex and requires full cooperation on your part at all times.

The following information is designed to answer some of the questions about the IVF-ER process. Ask any questions you might have, so that you fully understand each step of the process and are comfortable with all aspects of your treatment.

In making the final decision as to whether to initiate treatment, ask specific questions concerning treatment procedures, costs, the total number of treatment cycles performed by the IVF team, the number of pregnancies per cycle, and the number of live births per attempted cycle. These answers will help you make a decision regarding your individual treatment.

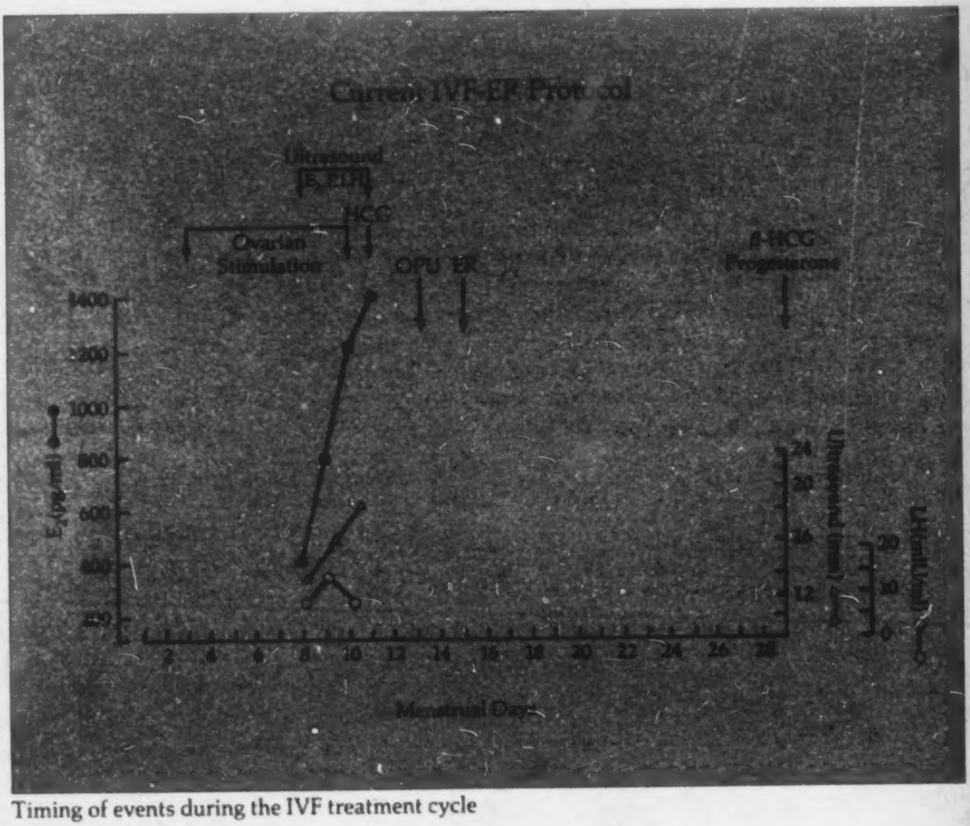
IVF-ER Program

The IVF-ER Program is made up of four steps:
1) Development of ovarian follicles (sac containing the egg), i.e., the ripening of eggs.
2) Collection of the oocytes (eggs).
3) Fertilization of the egg and growth of the embryo.
4) Replacement of the embryo back into the uterus.

The following discussion will briefly describe each step of the process and what will occur after the embryo replacement, if pregnancy does occur.

Follicular Development
Various hormonal products are used alone or in combination to induce several ovarian follicles to develop. These medications stimulate multiple follicles so that at the time of oocyte pick-up (OPU), several eggs are collected. This improves the chances for normal fertilization and development to occur.

These hormonal drugs have been used for over twenty years in women who do not ovulate regularly.



Timing of events during the IVF treatment cycle

There appears to be no increased incidence of birth defects, congenital abnormalities or an increased incidence of spontaneous miscarriage with the use of these medications. The reason why these drugs are used in IVF is to stimulate greater egg production; i.e., if more eggs and embryos are produced during the treatment cycle, there is an increased chance of pregnancy occurrence.

Following the use of these stimulatory drugs, a second hormone medication will be given by injection. It is necessary for this hormone to be given at the appropriate time of follicle development to allow the egg(s) to be prepared for ovulation or oocyte pick-up (OPU). Without the use of this medication, the timing and maturity of the eggs would be very difficult to assess.

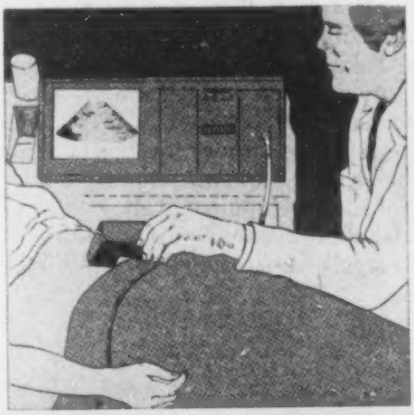
The stimulatory drugs usually are started on Day 3 of your menstrual cycle, and are used for up to 8 to 10 days depending upon the follicular development. The medications may be adjusted during the treatment cycle depending upon follicle growth.

4

Ultrasound Monitoring For IVF-ER

Ultrasound monitoring is used to follow follicle growth in the ovary. The ultrasound unit sends out sound wave signals that reflect off structures in the pelvis, and gives the physician an actual image of follicular growth on each ovary. Ultrasound usually is begun on Day 8 of the menstrual cycle and is painless. There have not been any harmful effects demonstrated to the developing eggs or early pregnancy with ultrasound use during these times.

Each day that you have an ultrasound scan performed, you will have a blood test. This blood will be analyzed prior to oocyte pick-up (OPU) to determine if hormonal levels are in the range expected to insure optimal egg production and maturation. The second hormone drug will be injected when hormonal and ultrasound parameters indicate that ovulation is about to occur.



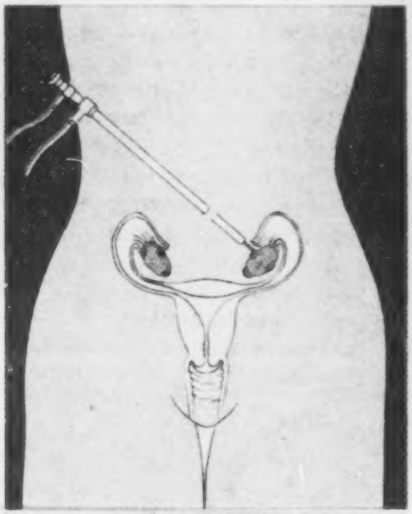
Ultrasound view of ripening follicles

Ovum Pick-Up

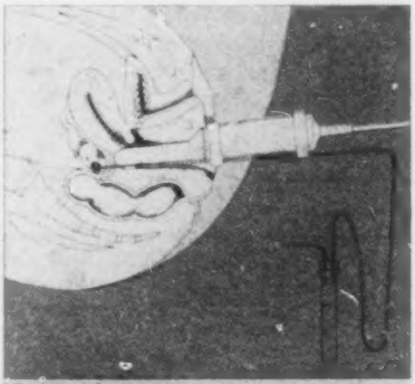
Eggs are collected by either a laparoscopic procedure or ultrasound-directed needle aspiration.

If laparoscopy is to be performed, an anesthesiologist will administer a light general anesthesia. The laparoscope is placed through a small incision beneath the navel. There are two small areas of puncture sites where the special aspiration system for the eggs will be placed and a holding forceps will be inserted. The incisions are closed with several stitches which will absorb in several weeks, leaving virtually no visible scars. During the laparoscopy, the eggs will be aspirated from the follicles.

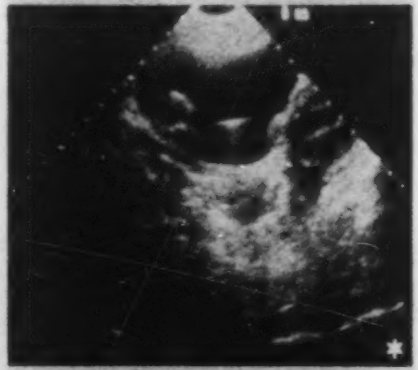
An alternative to laparoscopic ovum pick-up is ultrasound-directed needle aspiration. This technique avoids a surgical procedure and is performed under a local anesthetic. The most common approach is placing the needle through the top of the vagina into the ovary or through the back of the bladder into the ovary. In the hands of an experienced physician, ultrasound OPU has the same success as laparoscopic OPU. They can be used interchangeably.



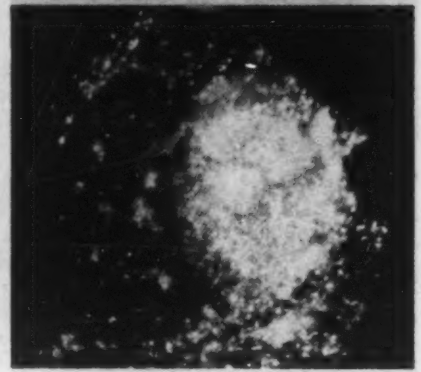
Laparoscopy and egg aspiration



Ultrasound aspiration

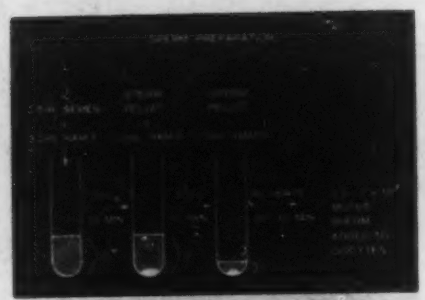


Ultrasound egg recovery

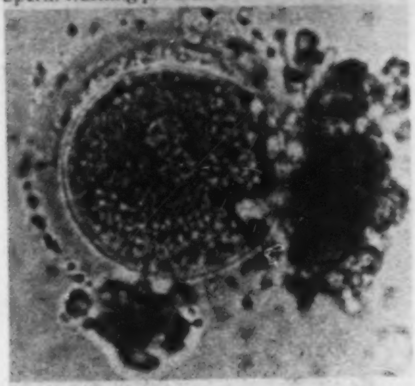


Human oocyte (unfertilized)

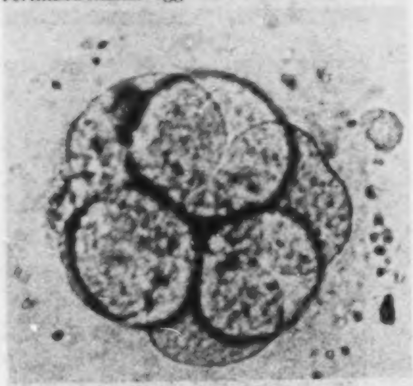
Oocyte Culture And Fertilization



Sperm washing procedure



Fertilized human egg



Human embryo

Once the eggs are received in the laboratory, they are placed in a special fluid medium and allowed to remain there for approximately 2-3 hours. Following the OPU, a semen sample is obtained by masturbation in a sterilized container and transported to the laboratory. The semen is washed, incubated and then placed in the medium with the egg.

The sperm and egg will be in the same environment for approximately 40 hours and will be examined for the first time approximately 18 hours after the time of insemination.

If the eggs develop normally, you will return to the hospital anywhere from 1-3 days later for the replacement of the embryo(s) into your uterus.

Embryo Replacement

The embryo replacement procedure is very simple and requires no anesthesia. A very fine catheter, or tube, is inserted into the uterus through the cervix, and the embryo(s) are transferred into the uterine cavity.

You may be required to stay in a reclining head down position for approximately 2-4 hours after the embryo(s) have been placed into your uterus. Activities after embryo replacement should be minimal for the first 24-48 hours. After that, you may resume your normal activities.

Treatment Cycles

If a treatment cycle is unsuccessful, you may be asked to wait 3–4 months before initiating another treatment cycle. This pattern can continue until pregnancy is achieved or until you have reached four complete treatment cycles. At that time, a consultation concerning the feasibility of proceeding with more attempts would be advised.

Reason For Cancellation Of A Treatment Cycle

The ability to monitor normal follicle development and maturation of oocytes is of utmost importance to insure a good outcome with egg collection. It is important to be absolutely sure that the timing of ovulatory response is precise. Therefore, if there are any questions about the follicle development or the timing of the hormone injection, the treatment cycle might be abandoned rather than proceeding with an OPU, which may ultimately fail. If it is detected that the Luteinizing Hormone level has increased (prior to OPU), the treatment cycle may be abandoned. The Luteinizing Hormone level is an indicator that spontaneous ovulation has begun. Therefore, the timing of the laparoscopy would be difficult, and the OPU might be cancelled. Reinitiation of another IVF cycle may be initiated after the onset of a subsequent menstrual cycle.

Cost Of The Program

IVF-ER is a costly treatment. The average cost will vary from center to center. However, you should expect to pay approximately $5,000 per cycle of IVF-ER. This includes the hospital, laboratory, surgical and medication costs.

All costs should be discussed prior to initiation of treatment.

Insurance Information

Some insurance companies are providing partial or full coverage for IVF-ER procedures. The IVF team can give you specific details regarding insurance coverage in your geographic region.

Common Patient Questions And Answers

Q. How do I know if IVF-ER is an appropriate therapy for me?

A. IVF-ER is utilized when no functional fallopian tubes are present or where the male cannot produce a normal number of sperm for fertilization to occur inside the female reproductive tract.

Q. Is there an increased chance of an abnormal child after IVF-ER?

A. To date, the incidence of birth defects in over 3,000 babies produced by IVF-ER are no higher than what is expected in normal pregnancy populations.

Q. Am I more likely to have a boy or a girl after IVF-ER?

A. The sex ratio is almost identical to that seen in the general population. The standard sperm preparation techniques for IVF do not select for one or the other gender.

Q. How many days am I involved during a treatment cycle?

A. From the time monitoring is begun until you can resume full activities after embryo replacement encompasses about 8 to 10 days. This occurs between cycle day 8 and 16 on the average.

Q. Will I experience any side effects from the drugs used to stimulate my ovaries?

A. As with any medication, side effects are possible. However, because the doses used are not high, few patients experience any significant side effects from the medications. It is important to discuss this with your physician.

Q. Is there any diet or exercise program that will improve my chances of success?

A. General parameters of balanced nutrition and adequate rest and exercise hold true. No specific dietary or vitamin regimens are known to enhance outcome.

Q. Should I have a laparoscopy or an ultrasound-directed aspiration for my egg collection?

A. Most egg collections can now be done by ultrasound aspirations. If there is a reason to evaluate your reproductive organs, for instance, to see if endometriosis has progressed or to view the status of your fallopian tubes, laparoscopy can be used to collect your eggs and view your reproductive tract.

Q. How does my physician know if my eggs have fertilized in the laboratory?

A. Once the egg fertilizes, two spots are seen (pronuclei). These disappear after 6 to 10 hours, and the egg divides into two cells, then four cells, and so on.

Q. On average, how many embryos is it safe to place back into the uterine cavity?

A. Most programs replace three or four embryos. This optimizes the pregnancy rate to be between 30% and 35%. The risk of twins is 12% to 15%, and the chance of having triplets is 2% to 4%.

Q. What happens if I produce more than four embryos during a treatment cycle?

A. Embryo freezing is utilized in several centers in the United States and overseas. Embryos can be frozen and stored for extended periods of time, and then thawed and replaced into the uterus. Several births have occurred in the United States from this procedure.

Q. Will I be on medications after the embryo replacement?

A. Most IVF programs use luteal phase support in the form of progesterone or hormone injections, or progesterone vaginal suppositories. There is a question whether this is necessary to support corpus luteum function, and at present the data are unclear.

Q. When will I know if I am pregnant?

A. You will have a blood sample obtained 11 to 14 days after embryo replacement, which will determine whether you are pregnant.

Q. Is there more of a chance for a miscarriage after IVF-ER?

A. There appears to be a somewhat increased risk of miscarriage after IVF (25% to 30%) compared to spontaneous pregnancies (15% to 20%).

Q. Does my age affect my pregnancy chances with IVF-ER?

A. Up to the age of 40, pregnancy statistics do not change dramatically. Above the age of 40, pregnancy rates decrease and the incidence of miscarriage increases significantly.

Glossary

Aspiration
The application of light suction to the ovarian follicle to remove the eggs.

Cervix
The lower section of the uterus that protrudes into the vagina and dilates during labor to allow the passage of the infant.

Corpus Luteum
A special gland that forms on the surface of the ovary at the site of ovulation and produces progesterone during the second half of the menstrual cycle. It is necessary to prepare the uterine lining for implantation by the fertilized egg.

Embryo
The developing individual from conception until approximately the end of the second month.

Endometrium
The mucus membrane lining the uterus.

Estrogen
12 The primary female hormone produced mainly by the ovaries from puberty to menopause.

Fallopian Tube
Either of a pair of tubes that conduct the egg from the ovary to the uterus. Normal fertilization takes place within this structure.

Follicle
The fluid filled sac in the ovary that has nurtured the ripening egg and from which the egg is released during ovulation.

Follicle Stimulating Hormone (FSH)
A hormone produced and released from the pituitary that stimulates the ovary to ripen a follicle for ovulation.

Implantation
The embedding of the fertilized egg in the lining of the uterus.

Insemination
The installation of semen into a woman's vagina for the purpose of conception.

Laparoscopy
Abdominal surgical exploration using a laparoscope (optic system) to view the fallopian tubes, ovaries and uterus.

Luteal Phase
The last fourteen days of the menstrual cycle after ovulation has occurred. It is associated with progesterone production.

Lutenizing Hormone (LH)
A hormone produced and released by the pituitary gland. In the female, it is responsible for ovulation. In the male, it stimulates testosterone production.

Oocyte
The egg cell produced in the ovaries each month. Also called the ovum (gamete).

Ovaries
The female sex glands with both a reproductive function (releasing eggs) and a hormone function (producing estrogen and progesterone).

Ovulation
The release of a mature egg from the surface of the ovary.

Progesterone
A hormone produced and released by the corpus luteum of the ovary during the second half of an ovulatory cycle. It is necessary for the preparation of the lining of the uterus for the implantation of the fertilized egg. It is also produced by the placenta during pregnancy.

Semen
The sperm and seminal secretions ejaculated during orgasm by the male.

Sperm (spermatozoa)
Male reproductive cells (gamete).

Uterus
The reproductive organ that houses, protects and nourishes the developing embryo/fetus. It is a hollow muscular structure that is part of the female reproductive tract and is the source of a woman's menses.

Ultrasound
A technique for visualizing the follicles in the ovaries and the fetus in the uterus, allowing the estimation of size.

Vagina
A tubular passageway in the female connecting the external sex organs with the cervix and uterus.

GIFT

Gamete Intra-Fallopian Transfer

Ricardo H. Asch, M.D.
and
Serono Symposia, U.S.A.

GIFT, or Gamete Intra-Fallopian Transfer, is a new procedure designed to help couples achieve pregnancies when other methods have failed.

This pamphlet was written by Ricardo H. Asch, M.D., who developed the technique, and was produced by Serono Symposia, U.S.A., a division of Serono Laboratories, Inc. Dr. Asch is now the Director of the University of California, Irvine (UCI)—American Medical International (AMI) Center for Reproductive Health Care.

The pamphlet is intended to familiarize you with the many aspects of GIFT: how it was developed, the actual procedure, and who is eligible for GIFT.

Also, answers to questions most commonly asked by patients are included.

After reading this pamphlet, we encourage you to discuss it with your physician if you have any further questions.

Serono Symposia, U.S.A. is committed to the education of both physicians and infertile patients. We're very pleased to bring you this pamphlet, and hope you find it useful.

Sincerely,

Leslie Nies

Leslie Nies
Vice President
Medical & Consumer Affairs

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Normal fertility

A normal pregnancy begins with the release of an egg from the woman's ovaries in a process called ovulation. The egg enters the Fallopian tube where it meets with sperm that have traveled from the vagina following intercourse. The sperm fertilize the egg.

The fertilized egg, now called an embryo, begins to divide, and in four to five days contains many cells (Figure 1). At this time, the embryo moves to the uterine cavity where it "floats" for another two days. The embryo then implants in the uterine wall (Figure 2).

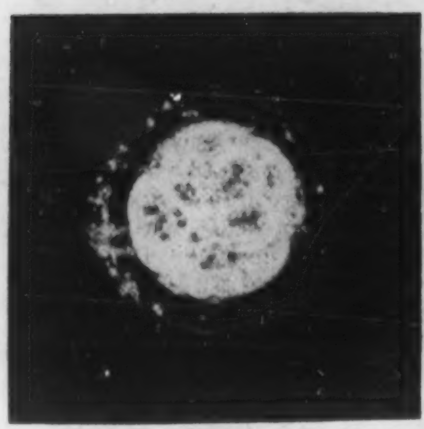

Figure 1

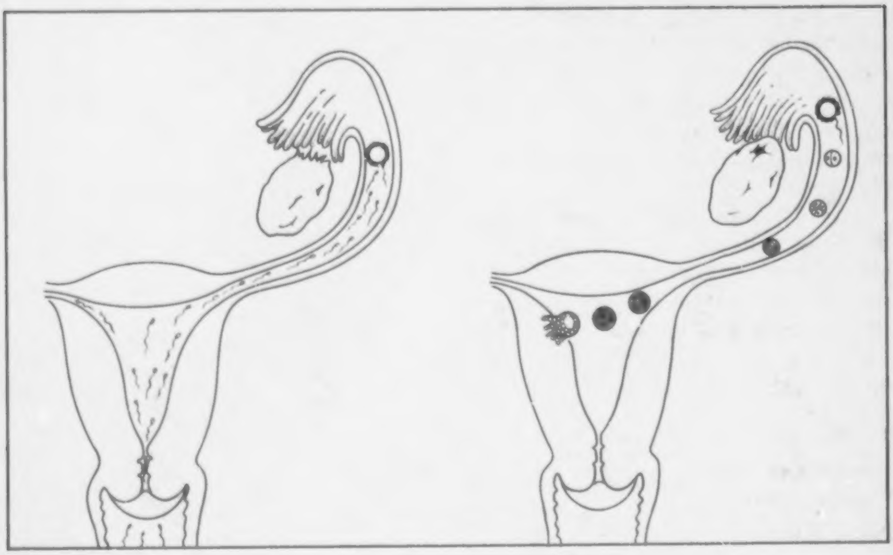

Figure 2

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GIFT

What it is and how it was developed

GIFT (Gamete Intra-Fallopian Transfer) is a new technique devised to achieve pregnancies in couples who have not been able to conceive using standard treatments for infertility.

The technique was developed by Dr. Ricardo H. Asch in 1984 while working as the Head of the Division of Human Reproduction of the Department of Obstetrics and Gynecology at the University of Texas Health Science Center at San Antonio.

Dr. Asch is a gynecologist with a subspecialty in reproductive endocrinology. After receiving his medical degree in his native Argentina he specialized in the area of infertility at the Medical College of Georgia and the University of Texas Health Science Center at San Antonio, Texas.

Currently, Dr. Asch is the Director of the UCI-AMI Center for Reproductive Health Care.

Among many of the areas of research on which Dr. Asch has focused his attention is the study of the transport of the sexual cells (gametes) throughout the entire female genital tract. It is this research that led to the original development of the GIFT technique.

In many cases, a major problem in determining the cause of infertility has been the inability to determine if the sperm and egg ever meet. Dr. Asch speculated that in cases of unexplained infertility and/or severe male factor infertility (low sperm count and/or motility), conception does not occur because either the egg or the sperm does not arrive at the site where fertilization is most likely to occur.

Ricardo H. Asch, M.D.

By placing the eggs and sperm together into the Fallopian tube, he believed that the prospects for a successful, full-term pregnancy would improve dramatically.

G-I-F-T stands for Gamete Intra-Fallopian Transfer. Essentially, the name explains the procedure. Gametes—the female's egg and male's sperm—are placed separately into a catheter and injected directly into the woman's Fallopian tubes during a surgical procedure.

Fertilization occurs in the woman's body, not outside or in vitro in a laboratory dish or in an incubator. GIFT mimics the way a normally fertilized egg would begin its journey to the uterus for implantation.

The GIFT procedure follows nature by allowing the eggs to fertilize and develop in the natural environment of the Fallopian tube, and then to make their way to the uterus for implantation according to a normal timetable.

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GIFT
The procedure

To prepare her body for the GIFT procedure, the woman receives hormones to stimulate development of the ovarian follicles, which are sac-like structures that contain the unfertilized eggs (Figure 3).

Administering hormones increases the chances of retrieving several ripened eggs, each capable of being fertilized by sperm once transferred to the tubes.

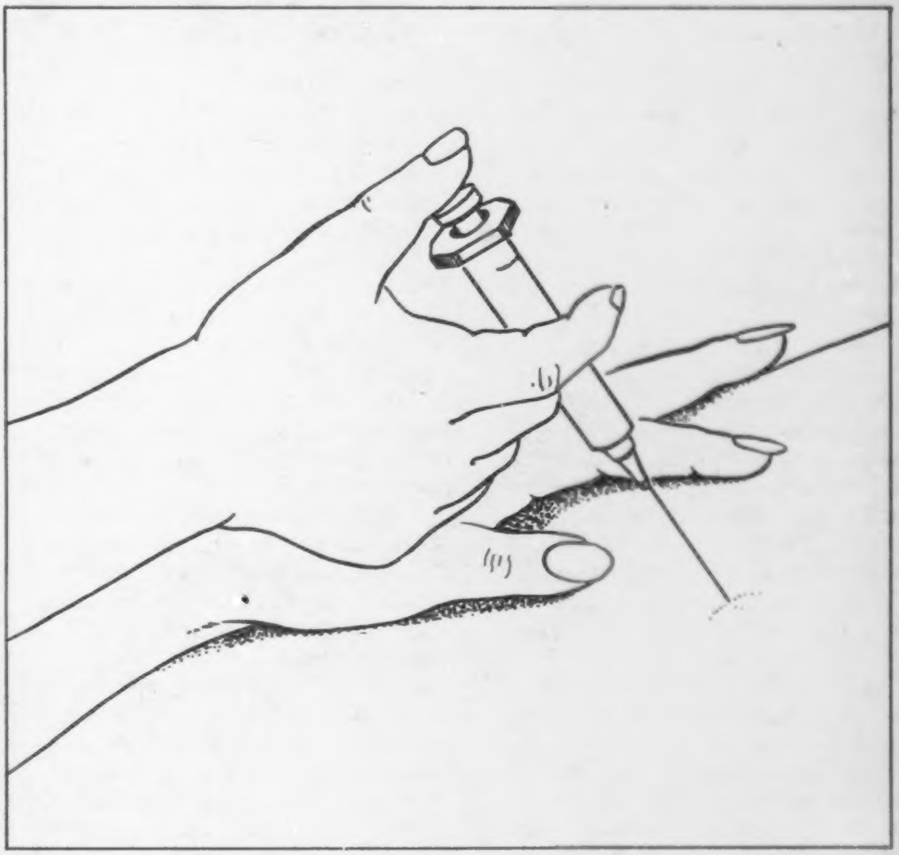

Figure 3

The hormones are administered for about seven to ten days. During this time, the patient is carefully monitored using laboratory tests, ultrasound scans and pelvic examinations (Figures 4a and 4b). When tests show the eggs are ripe and ovulation is imminent, the patient is admitted for the GIFT procedure.

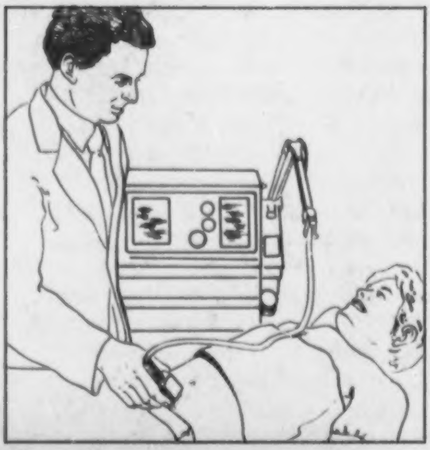

Figure 4a

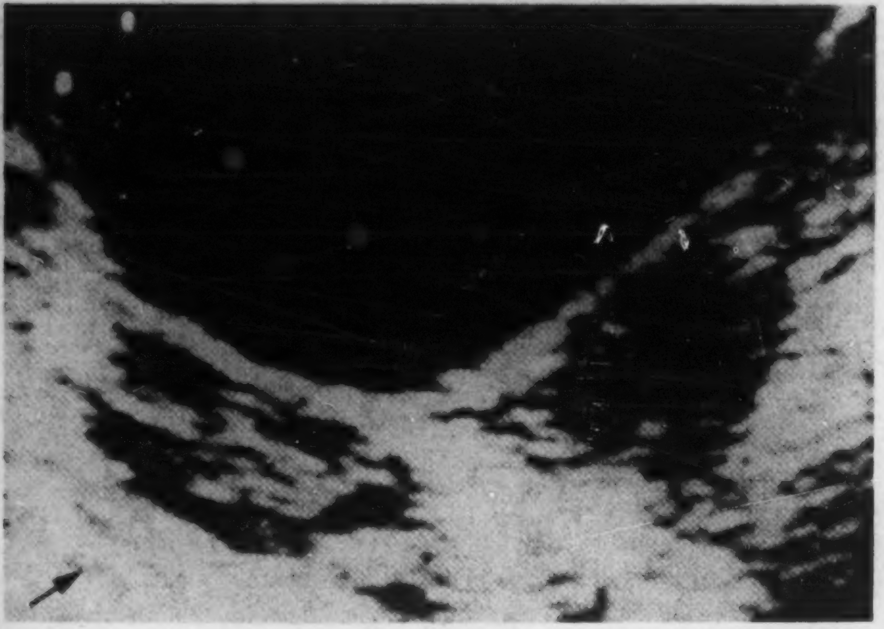

Figure 4b. Ovary with 5 developing follicles.

Approximately two hours before the procedure, a semen sample from the husband is obtained. In the laboratory, the semen sample is prepared by a technique of "wash and swim up." This means the semen is centrifuged, washed with a fluid and put in a test tube. Most of the sperm settle on the bottom, but the most active ones, those that "swim" to the top, are selected and loaded into the catheter.

The eggs can be retrieved from the follicles in the ovary several ways: some of them surgical (laparoscopy, culdoscopy, minilaparotomy) and some nonsurgical (ultrasound-guided aspiration) (Figures 5 and 6).

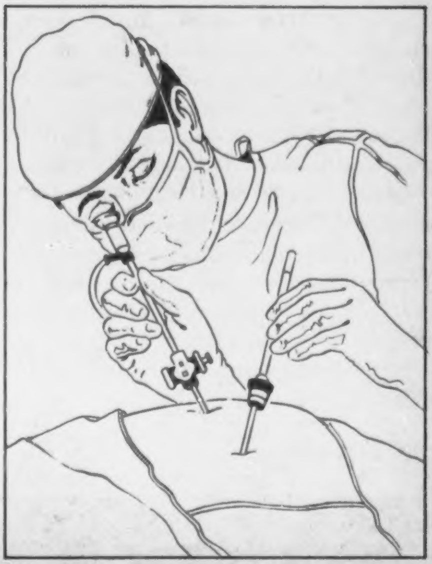

Figure 5

Figure 6. Translaparascopic follicular aspiration.

After aspiration of the follicles, the fluids are examined under a microscope by a trained biologist and their maturity determined (Figure 7). Eggs (Figure 8) and sperm (Figure 9) are then sequentially and separately loaded into a catheter and are then placed into each of the patient's Fallopian tubes (Figure 10). This can be achieved by several methods, the more common being laparoscopy or mini-laparotomy (Figure 11). You should ask your physician which method he or she recommends for you.

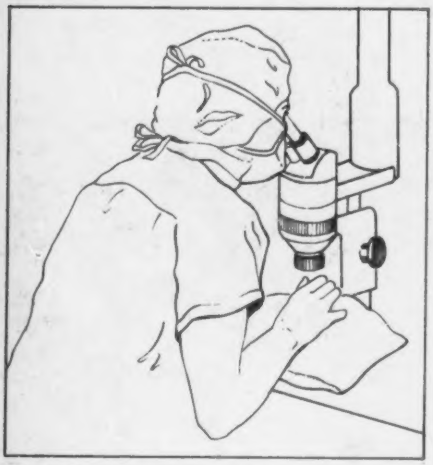

Figure 7

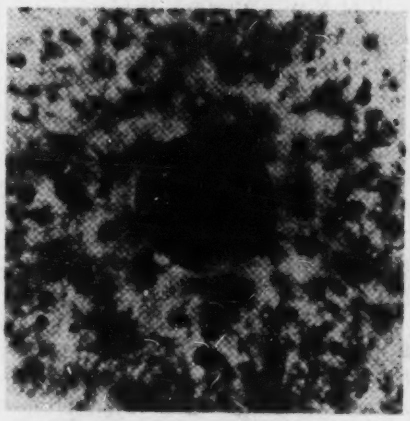

Figure 8

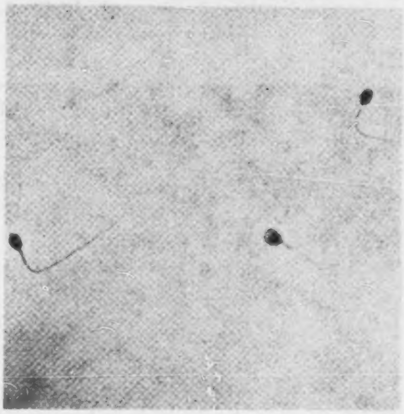

Figure 9

When the catheter is in place in the Fallopian tube, the eggs and sperm are injected into the tube using a special syringe.

The transferred gametes come together in the Fallopian tubes where the fertilization process is allowed to happen naturally. The resulting embryos are nurtured in the tubes, then move down into the uterus for implantation.

The GIFT technique is performed as a one-step procedure. The entire procedure lasts approximately 40 to 60 minutes, and the patient returns home either the same day or the next day.

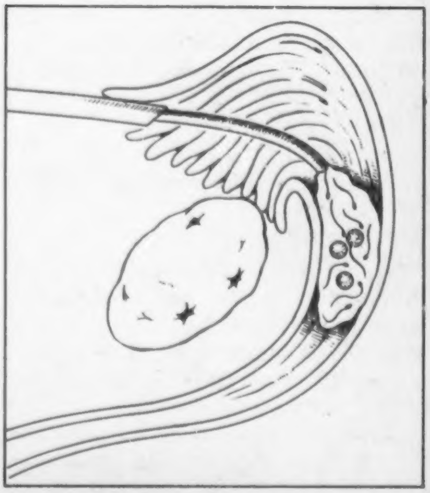

Figure 10

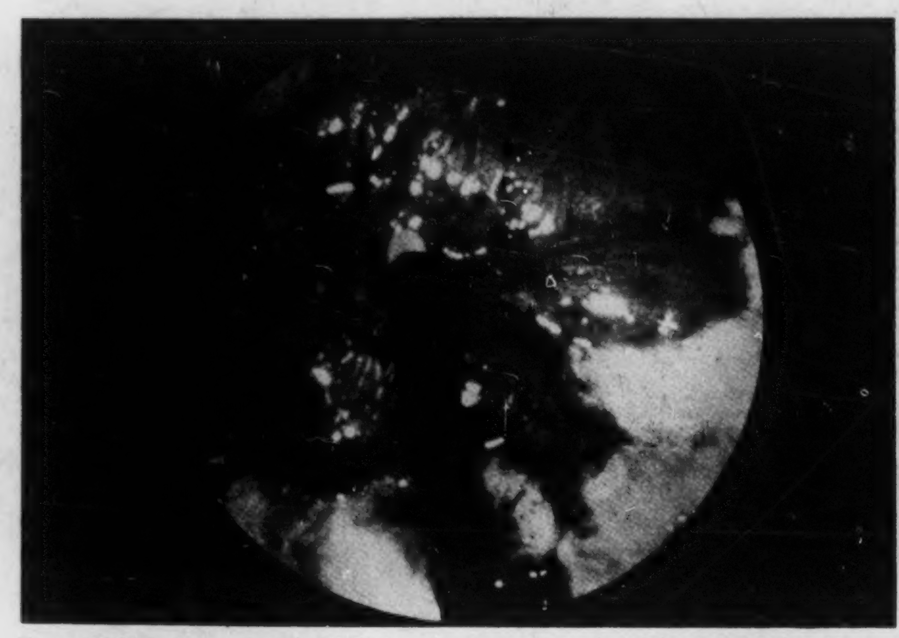

Figure 11. Translaparascopic GIFT, showing the catheter being introduced into the Fallopian tube through the fimbria.

Pregnancy can be confirmed using blood and urine tests approximately ten to twelve days after GIFT (Figure 12), and by ultrasound (Figure 13) approximately 25 days after GIFT.

Figure 12

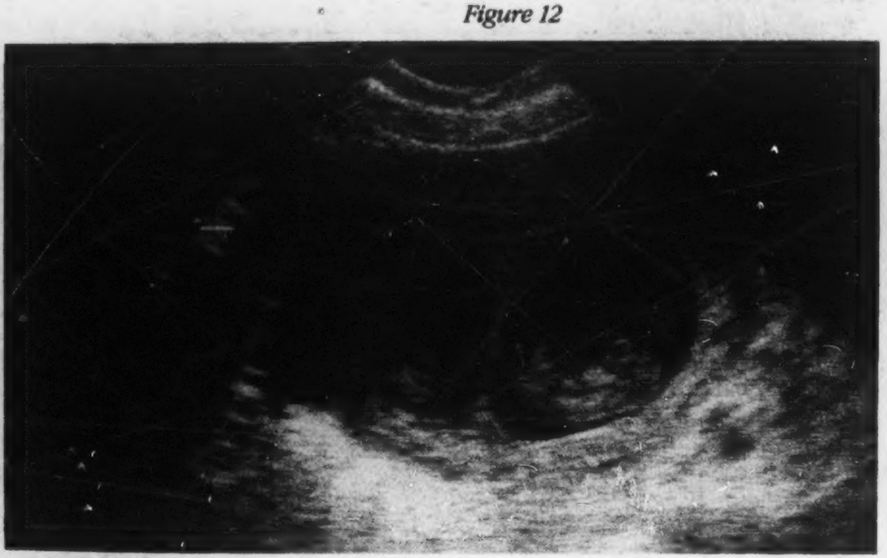

Figure 13. Pelvic ultrasound of a patient 53 days after the GIFT procedure, showing a twin intrauterine gestation.

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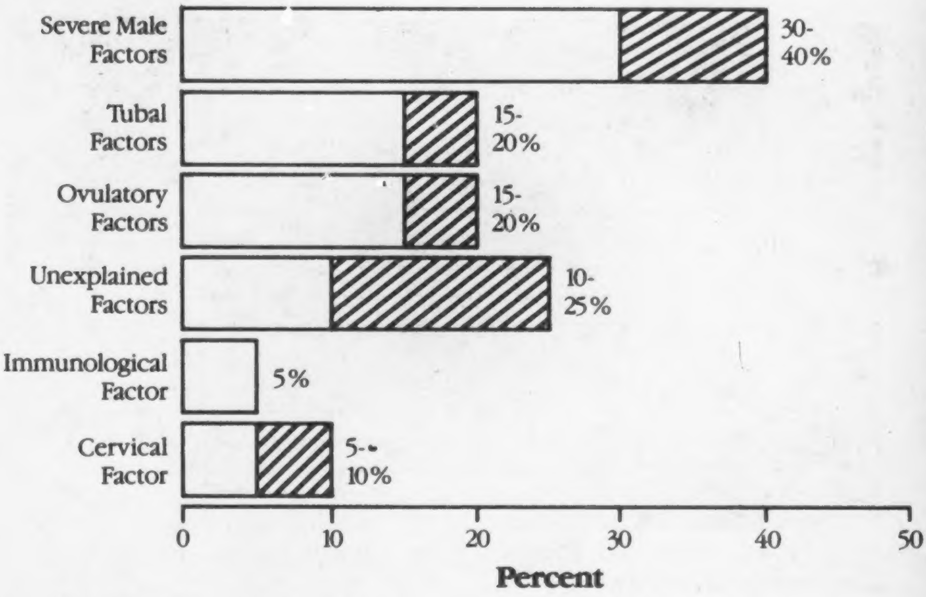
GIFT
Who is eligible?

The GIFT technique has proven successful in the treatment of infertility due to different causes. These include: unexplained etiology, severe male factor, endometriosis, cervical factor, immunological factor, a failure of donor artificial insemination, cases of deficiencies of egg pick-up by the Fallopian tube, cases of need of egg donation, and a combination of these conditions.

For the purpose of performing the GIFT procedure, it is imperative that the patient have at least one normal patent Fallopian tube. In the cases where both tubes are damaged and cannot be corrected with modern microsurgical techniques, IVF (in vitro fertilization) and ET (embryo transfer) should be indicated.

Percent of Factors Causing Infertility



MISCELLANEOUS FACTORS: Other unusual factors or a combination of two or more of the above factors can cause infertility.

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Common patient questions and answers

Q. Will the GIFT technique damage my ovaries?

A. There is no evidence to suggest that either the surgical procedure or the actual egg retrieval damages the ovaries.

Q. Will scar tissue around my ovaries make it impossible to retrieve the eggs?

A. Possibly, if the ovaries are entirely covered by scar tissue. The surgeon must be able to see the follicles in order to guide the needle to the proper spot for aspiration of the eggs. In some cases, ultrasound aspiration of eggs may be indicated.

Q. What if I ovulate before egg aspiration?

A. Once ovulation has occurred, it is practically impossible to aspirate the eggs. Just prior to aspiration, an ultrasound scan is performed to determine if the follicles are still intact. If the follicles have not ruptured, it is assumed that ovulation has not occurred and GIFT will be attempted.

Q. If eggs are not aspirated, or if the technique does not produce pregnancy on the first attempt, how soon can the procedure be repeated?

A. Approximately three months later, depending on the individual. The primary reason for the delay is to allow the patient's normal menstrual cycle to resume. The delay also helps avoid any cumulative effect from frequent anesthesias, and to prevent the repeated emotional stress that patients undergo during the GIFT cycle.

Q. Can we have intercourse during the two-week period before the GIFT procedure, and how soon after the procedure can intercourse be resumed?

A. Before the procedure is performed, it is recommended that the man refrain from ejaculating for the 48 hours preceding retrieval of the egg. This precaution assures that the semen sample will contain a maximum number of healthy, motile sperm. After the procedure, abstinence is recommended for five to seven days.

Q. What about other activities? How soon can I resume my normal routine?

A. It is recommended that the patient be sedentary for a full 24 to 48 hours following the surgical procedure. Strenuous exercises such as jogging, horseback riding, swimming, etc. should be avoided until a pregnancy is confirmed. Otherwise, the patient is free to return to her regular activities.

Q. How soon will I know if I'm pregnant?

A. Pregnancy can be confirmed using blood and urine tests approximately ten to twelve days after GIFT.

Q. I had my tubes tied (tubal ligation) several years ago. Would I be a candidate for GIFT?

A. No, not at this time. Women whose Fallopian tubes are blocked due to previous tubal ligation, infection or congenital defects are not candidates for GIFT. It is recommended that in these situations you attempt to undergo microsurgery of your tubes, or IVF-ET.

Q. Will my insurance cover the cost of GIFT?

A. Since the GIFT technique is essentially identical to procedures used to diagnose the cause of infertility, it is anticipated that many insurance carriers will pay for the procedure.

Q. Is there a possibility of multiple births following GIFT?

A. Yes, when more than one egg is transferred. Twins and triplets have resulted from GIFT. The statistical multiple pregnancy rate with GIFT is still undetermined. However, early studies suggest that about 30% of all term pregnancies resulting from GIFT are twins. (In the normal population the rate is one set of twins per 80 births and one set of triplets every 6400 births.)

Q. Is there an increased chance of birth defects if I become pregnant through GIFT?

A. There are no known ill effects. Abnormal embryos, even those produced through normal fertilizations, do not seem to mature. However, as with IVF-ET, any long-term effects of GIFT fertilization remain to be determined.

Q. How much time does the preparation for GIFT require?

A. Approximately two weeks. Fertility drugs are administered to stimulate the ovaries. Then, during the seven to 10 days prior to ovulation, the patient is monitored as an outpatient. Immediately before the GIFT procedure, the patient is hospitalized.

Q. What happens to any extra eggs that are aspirated from my ovaries?

A. In the event that there are more eggs aspirated from your ovaries than those transferred during the GIFT procedure, several options for their use will be discussed by your physician. These options include in vitro fertilization, embryo freezing and/or donation to another infertile woman. Pregnancies resulting from egg donation and GIFT have already occurred in women with premature menopause and nonfunctioning ovaries.

Q. Are there any psychological effects due to the GIFT treatment?

A. The entire GIFT procedure has many steps: traveling to the center's location, daily injections, ultrasounds, blood drawings, surgery, waiting for the results of the pregnancy tests, etc. Each of these steps plays an important part in the anxiety and emotional stress that infertile couples undergo when attempting a GIFT cycle.

Emotional support is given by the infertility specialists and the entire GIFT team. Patient support groups such as Resolve may also play an important role in education and guidance. Ideally, psychological evaluation of every couple prior to and after the GIFT procedure will prevent unusual reactions in cases of failure to achieve a pregnancy.

Glossary

Adhesion

Scar tissue bands attached to organ surfaces, capable of connecting, covering or distorting organs, such as tubes, ovaries, uterus, and bowel.

Cervix

The lower section of the uterus that protrudes into the vagina and dilates during labor to allow the passage of the infant.

Corpus Luteum

A special gland that forms on the surface of the ovary at the site of ovulation and produces progesterone during the second half of the cycle. It is necessary to prepare the uterine lining for implantation by the fertilized egg.

Culdoscopy

Introduction of an optic system through the vagina to visualize the pelvic cavity.

Embryo

The developing individual from conception until approximately the end of the second month.

Endometriosis

The presence of endometrial tissue (the normal uterine lining) in abnormal locations such as the tubes, ovaries and peritoneal cavity.

Endometrium

The mucus membrane lining the uterus.

Estrogen

The primary female hormone produced mainly by the ovaries from puberty to menopause.

Fallopian Tube

Either of a pair of tubes that conduct the egg from the ovary to the uterus. Normal fertilization takes place within this structure.

Fimbria

The fringed and finger-like outer ends of the Fallopian tubes.

Follicle

The fluid-filled sac in the ovary that has nurtured the ripening egg and from which the egg is released during ovulation.

Follicular Phase

The first half of the menstrual cycle when ovarian follicle development takes place.

Follicle Stimulating Hormone (FSH)

A hormone produced and released from the pituitary that stimulates the ovary to ripen a follicle for ovulation.

Implantation

The embedding of the fertilized egg in the lining of the uterus.

In Vitro Fertilization-Embryo Transfer (IVF-ET)

A procedure in which an egg is removed from a ripe follicle and fertilized by sperm outside the human body. The fertilized egg is allowed to divide in an incubator for about two days and then is inserted into the uterus of the woman.

Laparoscopy

Abdominal surgical exploration using a laparoscope (optic system) to view the Fallopian tubes, ovaries and uterus.

Luteal Phase

The last fourteen days of the menstrual cycle after ovulation has occurred. It is associated with progesterone production.

Luteinizing Hormone (LH)

A hormone produced and released by the pituitary gland. In the female it is responsible for ovulation. In the male it stimulates testosterone production.

Minilaparotomy

A surgical procedure that consists of a very small suprapubic incision, which allows both follicular aspiration and Gamete Intra-Fallopian Transfer (GIFT).

Oocyte

The egg cell produced in the ovaries each month. Also called the ovum (gamete).

Ovaries
The female sex glands with both a reproductive function (releasing eggs) and a hormone function (producing estrogen and progesterone).

Ovulation
The release of a mature egg from the surface of the ovary.

Progesterone
A hormone produced and released by the corpus luteum of the ovary during the second half of an ovulatory cycle. It is necessary for the preparation of the lining of the uterus for the implantation of the fertilized egg. It is also produced by the placenta during pregnancy.

Semen
The sperm and seminal secretions ejaculated during orgasm by the male.

Sperm (spermatozoa)
Male reproductive cells (gamete).

Tubal Patency
Unobstructed Fallopian tubes.

Uterus
The reproductive organ that houses, protects and nourishes the developing embryo/fetus. It is a hollow, muscular structure that is part of the female reproductive tract and is the source of a woman's menses.

Ultrasound
A technique for visualizing the follicles in the ovaries and the fetus in the uterus, allowing the estimation of size.

Vagina
A tubular passageway in the female connecting the external sex organs with the cervix and uterus.

Suggested Readings

Andrews LB: *New Conceptions: A Consumer's Guide to the Newest Infertility Treatments.* New York: St. Martin's Press, 1984.

Asch RH, Balmaceda JP, Ellsworth LR, Wong PC: Gamete intra-fallopian transfer (GIFT): A new treatment for infertility. Int J Fertil 30:41-45, 1985.

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Corson SL: *Conquering Infertility* Norwalk, CT: Appleton-Century Crofts, 1983.

Insights Into Infertility Randolph, MA: Serono Symposia, U.S.A., 1985.

Mahlstedt P: The psychological component of infertility. Fertil Steril 43:335-336, 1985.

Menning BE: *Infertility: A Guide for the Childless Couple.* Englewood Cliffs, NJ: Prentice-Hall, 1977.

Chairman **Wyden**. It is the practice of our subcommittee to swear all the witnesses who come before us.

Do either of you have any objection to being sworn today?

Ms. **Williams**. No.

Ms. **Petter**. No.

[Witnesses sworn.]

Chairman **Wyden**. Thank you both very much for your work. Ms. Williams, why don't we begin with you. I know that these are very difficult and very private issues for someone to discuss at a congressional hearing and I just want to thank you for your willingness to give our effort such a boost. We will make your prepared remarks part of our hearing record in their entirety. If you would like to, perhaps you could just summarize your key concerns and speak in any fashion that is comfortable for you.

TESTIMONY OF JO BETH WILLIAMS, HONORARY CHAIR OF THE NATIONAL INFERTILITY AWARENESS WEEK

Ms. **Williams**. Thank you, Congressman Wyden. I really appreciate what your committee is trying to do. As a person who has been infertile myself I can tell you that everyone who faces this is extremely vulnerable and that person will pretty much try anything, any kind of treatment, pay a lot of money, and listen to what doctors tell us because we are desperate.

I wanted to come here today and tell you about my experiences. I read the testimony from last year's hearing and I have heard and read a number of horror stories about people being taken advantage of by unscrupulous doctors. Fortunately, that is not my particular situation.

But I think that my situation is probably a much more common one. Eight years ago my husband and I decided that we wanted to have a baby and we assumed that when we stopped using birth control we would get pregnant. When it didn't happen the first year my gynecologist assured me that it would happen very soon and I believe him, because our careers had kept us separated over a period of time and I thought perhaps that was the problem.

However, after 2 years it hadn't happened and my doctor suggested that I take my temperature every day and keep a chart of my cycle, which is not an easy thing to do, I don't think I ever really did it correctly, but I did it for the next 5 years and sex for us became timed around that cycle chart. Not very romantic. But we weren't desperate yet at that point.

One thing my doctor didn't tell me was that if you don't conceive after 6 months of trying you are considered to have fertility problems.

The third year I had a laparoscopy and no abnormality was found. My doctor still didn't tell me that the problem I had could be considered infertility. But I knew something was wrong and so I felt I should go to an infertility specialist.

However, my problem was I didn't know how to find an infertility specialist because it seems like all gynecologists, including the man I had been going to, claimed to be specialists in infertility. Really, the only recourse I had was to listen to the recommendations of friends.

So I spent the next 2½ years going to several doctors who were gynecologists and claimed that they also did infertility. We tried a number of things. We continued to take our temperature. We tried ovulation tests. My husband had sperm tests, et cetera.

By the fifth year we were doing vaginal inseminations, which meant that I was racing to the doctor with my husband's sperm in a jar. That was pretty much what sex had become for us. We began to wonder if this dream that we wanted so badly, to have a baby, was going to destroy us as a couple. We didn't know why we weren't getting pregnant and everybody just seemed to tell us, relax and not think about it which isn't possible because at that point I would cry every time I saw a mother and a baby. This was about the sixth year of trying, I guess. I felt angry and jealous every time I saw a pregnant woman. When several of my friends became pregnant I couldn't be around them because I found it too painful.

I had a tremendous sense of failure. It was so strong that I began to feel that I must be guilty of something but I didn't know of what. I felt like I was being punished.

I felt like the fact that I couldn't do the very thing that my body was designed to do, to conceive and carry a child, must mean that I wasn't fully a woman in some way.

All my other accomplishments in life seemed to fade into the background in the face of this failure.

Every month when I got my period I would cry and become despondent. My husband would try to cheer me up but I knew that he was angry and hurt each month, too. A sense of hopelessness began to creep into our lives. We didn't know where to turn. We felt like failures and so we didn't feel comfortable discussing the problem with our friends and our relatives. I didn't know about the existence of RESOLVE then, an organization to help infertile couples.

We were lucky because we became friends with a couple who were having similar problems, and through them I finally found a doctor who was a specialist in infertility. But this was after 6 years of trying to get pregnant and with each year I grew older. I heard the biological clock ticking louder, and I became more and more desperate. I was afraid that if we kept trying and failing that we would eventually be too old to be ideal adoptive parents.

So when I found this man, this infertility specialist, I felt relief because he clearly understood what I was going through. He recommended I see a counselor to help me with the emotional weight I had been carrying.

Eventually, I had surgery and fibroids were removed, and 4 months later I became pregnant. We were ecstatic and I fell in love with every baby I saw. I shopped for baby clothes. We thought up names. At 8 weeks we had the joy of seeing our baby's heart beat on a sonogram. At 12 weeks during a routine sonogram the radiologist informed us that the baby had died and no one knew why, these things just happen. As we were looking at the image on the screen of our little dream which had died, we began to cry and hold each other, whereupon we were asked to leave the room to allow the next patient in. I immediately had a D&C and felt as if my heart had been cut out as well as the pregnancy. Over the next few months I really began to wonder if I might lose my mind.

Fortunately, my infertility specialist sent me to see the man he felt had the best in vitro program in Los Angeles. This doctor told me his results statistics. So I went in pretty much knowing what our chances were and I didn't have great expectations, but I carried secret hope in my heart. There is that little seed of hope that never seems to die when you really want to have a baby.

I was very fortunate to have found this in vitro program. This doctor was caring and concerned and positive without building false hope. We did the GIFT procedure and to my surprise I became pregnant again. However, I began to have spotting very early so it was not a shock when the pregnancy turned out to be a tubal. I was one of the unlucky 1 or 2 percent of women doing GIFT who had ectopic pregnancies.

After the second loss we decided to try to adopt and now we have a beautiful baby boy. However, we want another child and so we are planning to give GIFT or in vitro another try. As I said, that seed of hope never seems to die.

I wanted to tell you my story because in a way I am lucky, I am fortunate enough to have had enough money to pay for these very expensive procedures, most of which are not covered by insurance. Also, I did eventually find people who could help me but it took me 6 years of trying and numerous doctors before I did so.

I live in a large metropolitan area and even I had a difficult time getting the kind of information I needed about who could really help me. I have many friends and relatives who are having fertility problems. I know how desperate and vulnerable they are. They will try any treatment. They will listen to anyone who says they can help you. The drive to have a baby is that strong.

The doctors I dealt with were all honest and kind men, but I felt that they should have been more open about their limitations and referred me to others who really could help me. The years were slipping away and the age factor is a vital one in infertility.

Now, I have heard real horror stories from friends about unnecessary surgeries, huge fees, doctors who can't even remember the names of the patients they have been treating for years. I believe it is cruel to put people who are already emotionally battered in the desperate position of not knowing how to find the right care. There must be ways to protect us, to make information available to us.

We, the infertile couples need to learn what questions to ask. We need to know where we can get the right answers. Thank you.

[Ms. William's statement may be found in the appendix.]

Chairman **Wyden**. Thank you very much. I'm quite clear and quite certain that these are very, very difficult things to talk about and just the fact that you would come and speak out in the way that you have, it seems to me, it makes it less likely that other people will face these problems.

I will have a couple of questions in a moment, but I just want you to know how much I admire your willingness to speak out on something that for millions of people is a very private and personal matter.

Our next witness will be Ms. Petter. We welcome you. We will make your prepared remarks part of our hearing record in their entirety, if you would perhaps in 5 minutes or so summarize your principal concerns that would be helpful.

TESTIMONY OF ANN PETTER, PRESIDENT, RESOLVE, BOSTON, MA

Ms. PETTER. Good morning, Congressman Wyden. Thank you so much for asking me. Good morning again, Jo Beth, thank you so much for being here. We all need you.

RESOLVE is a nonprofit organization incorporated in 1974 dedicated to providing emotional support, referrals, information, education, and advocacy to the infertile population. We are a membership organization supported primarily by membership dues, literature sales, direct mail solicitation to our members and friends. We represent over 15,000 people and 51 chapters from Maine to Los Angeles.

The chapters specialize in telephone response, support groups, informational symposia, and work shops. The national office maintains a list of surveyed infertility specialists and medical contacts throughout the United States. It produces a newsletter and widely acclaimed fact sheets on a range of topics such as what is an infertility specialist, male infertility, private adoption, et cetera.

Our intent is to inform patients also known as consumers, so that they may make informed choices. The name RESOLVE implies making an informed choice, resolving one's infertility problem by making an informed choice.

In fact, one might consider us a consumer advocacy organization. As a consumer advocacy organization we are concerned with the level of trust between the consumers and vendors, or in this case, the patient and the medical practitioners.

The difference between a patient seeking medical help and anyone of us and the dishwasher salesperson is that the patient by virtue of his or her medical situation is suffering from anxiety which may make him or her extremely susceptible to false hopes and misinformation.

In the case of the appliance purchaser, many regulations have been made to equalize the participants and to reduce the anxiety which may be present when one party knows considerably more about the subject at hand.

When infertile people decide to purchase the services of an IVF clinic or program they probably have been through years of infertility tests and procedures. They face a procedure which they may consider the last hope to have a biological child or a procedure which will further drain them physically, emotionally, and financially. In a word, they are vulnerable.

Let me quote from two recent letters to the editor in our newsletter. The first one, these are responses to an article about an IVF experience which was very easy and simple, the person had a baby on the first attempt and didn't seem to suffer too much of the emotional rollercoaster.

The first is:

> I have undergone four unsuccessful IVF attempts. As a person who has weathered the poor success rates, the pain and the emotions described including a cycle in which five eggs were retrieved and did not fertilize, perspective IVF couples are unprepared for the emotional rollercoaster and let down. As painful as these realiza-

tions are it is far more painful and harmful to enter into this imperfect procedure with unrealistically high expectations.

Only those people involved as patients in IVF can comprehend the devastation an unsuccessful outcome can bring, especially if their hopes have been unrealistic. My IVF clinic advised me to try IVF until it worked.

This is from a DES daughter with a T-shaped uterus.

The second letter says:

> I am an infertile woman who has undergone five IVF attempts and I am speaking on behalf of other couples with typical IVF experiences, easy experiences are not the norm. Although optimism and hopeful messages are very important to all infertile people it is equally as important to balance these messages with realism. No mention was made of IVF's extreme emotional pressures and financial burden.
>
> IVF is hope blended with a heavy burden of despair and loss for most of us. It is best to try to prepare hopeful IVF candidates realistically for this bittersweet experience. Current IVF clinics success rates tend to conceal reality and we had hoped that RESOLVE could do better.

I could of course go on at great length about the calls we receive about IVF and how very difficult it is for people and how confusing and how frightening when they feel that they cannot trust the information they are receiving about this perceived answer to their problems.

Now, RESOLVE is concerned about their confusion and about the potential for misleading them as well as other problems which IVF clinics as patient or profit driven medicine may produce.

To alleviate some of these problems we propose the following suggestions. Let me just say that—I'm going to skip over the parts about we really uphold all AFS does to provide standards and that we definitely want the clinics regulated. The idea that the clinics are not as regulated as your average dental lab is kind of appalling.

But we would like to add one request about these standards and that is, it is very easy for both physician and patient to lose sight of the ultimate goal. High tech reproductive techniques are exciting. So exciting that everyone may forget about the baby, which is the whole impetus behind this effort.

We suggest that after several IVF attempts an outside referral be required for counseling the IVF patient. In-house counseling is fine for support while the patient is dealing with the rollercoaster of emotions which IVF engenders. But when it comes to a decision to move on, however—whatever that solution might be, whether it would be to adopt a child, whether it would be to decide to have a child-free life, when that time has come objectivity is needed.

If this could be incorporated into standards for IVF clinics and programs it would increase the patient/public's belief in the trustworthiness of the medical facilities providing the procedure.

However, most importantly RESOLVE would like to see truth in advertising from the IVF clinics. We have heard of clinics quoting the national statistics rather than their own in their promotional material. While this is unusual, it is certainly difficult to fare it out, the take home baby rate of any particular clinic or program.

A number of babies compared to what? A number of women who are enrolled in the program? A number of stimulation cycles? Number of transfers?

Let me quote again from RESOLVE's newsletter of December 1988 from an article by Michele Savel, originally printed in the August 1988 Obstetrics and Gynecology. Dr. Savel said:

> A couple recently came into my office and the wife asked me, doctor, we are looking for the best IVF program, what is your success rate. I said, I want to tell you the whole truth. What do you mean, she replied, doesn't every IVF program tell the truth? I am confident, I said, that doctors and IVF team members do not lie. The problem is mathematical. You see every fraction has a numerator and a denominator. In IVF the numerator is the number of pregnancies. Pregnancies or babies?
>
> All pregnancies do not result in babies in a fraction of the truth. The numerator may represent a positive pregnancy test or a term pregnancy.
>
> I continue my discussion of a fraction of the truth by talking about the denominator. The denominator I said is even more confusing to explain. It can represent patients, sight retrievals, or embryo transfers.
>
> For example, let's pretend a new IVF clinic has one patient who goes through the procedure five times. The first time they fail to retrieve an egg; and the second time the retrieved eggs fail to fertilize. The last three cycles result in embryo transfers and the patient conceives on her fifth attempt. What is the success rate? The patient responded, the IVF success rate is one pregnancy per five sight retrievals or 20 percent. One pregnancy per three embryo transfers or 33 percent. Or one pregnancy per one patient or 100 percent, depending on which denominator you use. That's right, I told her. But don't forget about the numerator in the fraction of the truth.
>
> Also there are time and patient selection. You see, if IVF success rates represent only a particularly successful interval of time the results will seem higher. Results will also seem increased if they exclude older patients or men whose sperm counts are extremely low, I explained.

Wanting to put your best foot forward is very human. In this success-oriented culture it is understandable that IVF clinics and programs want to sound successful. However, what they are doing in some cases is obfuscating. It is important for a layperson to decipher the claims of these programs. It is essential that perspective patients know what their chances are, not only to conceive but to achieve that ultimate goal, a baby.

If a woman is the ideal candidate right now it might be hard for her to discern her real chances given the current kinds of brochures that are available. Relating the data to her own diagnosis or age may be even more difficult. The impact of one's diagnosis on success rates should be clarified at the very start for each and every perspective IVF participant. What is your diagnosis and your age should be one of the primary questions an applicant is asked.

In short, we are asking for truth in advertising for fairness. IVF, GIFT, and other high tech procedures are clearly patient driven medicine which is of course sometimes synonymous with profit driven medicine.

RESOLVE knows that to establish a new clinic is costly. Malpractice insurance is high. Salaries for highly trained personnel and renting equipment are expensive. These costs must be covered, we realize that, and we are working across the country for insurance coverage for these costs.

However, covering these costs should not be at the expense of the patient or medicine's good name. Let us maintain the trust by giving a clear, comprehensible, and truthful information.

I thank you very much and I will be happy to answer any questions.

[Ms. Petter's statement may be found in the appendix.]

Chairman Wyden. Thank you very much, Ms. Petter.

Let me begin if I might with you, Ms. Williams. It seems like it took a long time for you to get correct diagnosis and in effect be able to get the proper kind of treatment. Is it your sense that this delay made it more difficult for you to conceive?

Ms. **Williams**. I think certainly it contributed to the problem because as I get older it becomes—as anyone gets older—it becomes increasingly difficult to conceive.

I also think the stress factor increases over the number of years that you are trying and certainly stress is one of the things that contributes to infertility.

Chairman **Wyden**. Now my sense from your testimony is that you felt that most of the professionals involved, the doctors and the clinics, were not exploitative or trying to deliberately take advantage of you. But I gather that you felt most of them didn't give you very useful information and direct you so that you could deal with your situation; is that correct?

Ms. **Williams**. Yes; I certainly feel that all the doctors I dealt with were good doctors, were honest men, and were kind men. I certainly don't think they were deliberately trying to exploit me in any way.

I think the difficulty is that they were calling themselves infertility specialists and I don't think most of the men, of the several men I saw before my last two doctors were reproductive endocrinologists. The treatments that I was being given, particularly in the first 3 years were basically kind of relax and it will happen.

I feel that there should have been more of an openness between the doctor and the patient. I mean, as a patient you feel a little timid about saying, doctor, I don't think this is working, can you tell me who else I should go to.

But ultimately I had to do that. I think that doctors should say, I don't know what the problem is but I would recommend that you see so and so because this is his specialty.

Chairman **Wyden**. Was it your sense that some of these practitioners were withholding information or was it your sense that perhaps they didn't know that much about fertility themselves?

Ms. **Williams**. I don't think they were withholding information from me at all. I think they were good gynecologists who didn't have that much training in the more difficult aspects of infertility.

Chairman **Wyden**. In terms of the couples, couples that you have seen and worked with—is it your sense that many of them are just so desperate that they will try almost anything?

Ms. **Williams**. Absolutely; I think the emotional factor here is so strong as the years go by and you are not conceiving and the pressure mounts and you want to have a baby so badly. I mean, as a woman I know—before I adopted my son I ached to actually hold my own child.

You do become desperate. You go through periods where you cry for no reason and you want someone to help you. If someone says they can help you, if they say stand on your head after sex you will try that. If your friends say, gee, I held a chicken foot up and it worked for me you will try that. If a man says, thousands and thousands of dollars, if you can afford it you will try it.

Chairman **Wyden**. Recognizing that your situation is atypical from the standpoint of resources, how much did you end up spending over the years on the variety of treatments and services that you tried?

Ms. **Williams**. I haven't really added it up, but I mean I'm sure it's somewhere $10,000 and $20,000. Some of which was covered by insurance because the procedures claimed were not necessarily clearly infertility procedures.

Chairman **Wyden**. The only other question I had for you is, what is your assessment of the kind of advertising that is going on in the fertility field today?

Our committee has uncovered a number of cases that concerned us greatly. But I think it's important to see this in the eye of a patient, of a consumer. What was your assessment of some of the advertising?

Ms. **Williams**. When I went into the in vitro program it was about 2 years ago and I was recommended—this program was recommended to me by another doctor, so I wasn't really too much aware of the advertising involved at that time.

Over the last year or so I have become more aware of it and it seems to me that there has become sort of a competition between clinics and people are making these kind of amazing claims. I have a number of friends who have done in vitro and friends who are interested in it and no one seems to be able to get any clear answers about what a particular clinic's statistics are and what they mean. I think it's very important that that information be available to us.

Chairman **Wyden**. Thank you for your help.

Ms. **Williams**. Thank you.

Chairman **Wyden**. Ms. Petter, just a couple of questions for you, if I might. You, in your testimony, used the term obfuscation and it clearly addresses this question of whether the advertising is not as straightforward and is objective as it should be. Could you give us some examples of the kind of obfuscation that your group has uncovered?

Ms. **Petter**. I don't think I can give you any specific examples. I probably should have brought a flyer or two. It seems to me obfuscation tends to be kind of a PR obfuscation.

As I was sitting here I was thinking about that a little bit, that perhaps some clinics may have employed a PR person and some of these things seem very PR. It may not even be the doctors who are doing this, but just putting their best foot forward.

It's generally a situation of the numerator and the denominator sort of thing. Saying we have a success rate of 33 percent when they're talking about a success rate of perhaps clinical pregnancies and not talking about the number of spontaneous abortions or something.

Chairman **Wyden**. I have an ad here from the Fertility Institute of Boca Raton—and it says that they are producing some very impressive results. It's a pretty large ad. Then they say: "Our success rate is an impressive 30 percent, well above the national average." As you read something like that how would you react to that?

Ms. **Petter**. I would come back to my quote about the numerator and the denominator. I would want to know what they were, you know, was it per person that went in the door? What are they talking about? It is not clear what they are talking about.

Chairman WYDEN. Only one other question for you, if I could. Do you favor additional Government regulation from the standpoint of credentialing or certifying these clinics? The step that we're taking today is the first step to try to get out clinic-specific information about IVF. I know of your views on insurance and the like. But do you favor certifying clinics by the Federal Government or licensing clinics by the Federal Government? Are you advocating those kinds of things at this point.

Ms. PETTER. I would say that we are not advocating them at this point. Not that we don't think there should be standards and that standards should be met. I'm sort of confused about the policing or enforcing of those certifications and whether it will be at a State level or whether it will be at a national level. I'm not certain that I have seen a model of that. I think that we would like to see some sort of model before we endorsed.

Chairman WYDEN. I think that's a sensible position. One of the things that I'm looking at now is the idea of trying to get some standardized definitions of services and treatments in this field. Would something like that be helpful in your view?

Ms. PETTER. Yes.

Chairman WYDEN. Thank you both. You have been very helpful and we're going to want to consult with both of you as we go forward with our efforts. Thank you again for coming and for speaking out as you have.

Ms. PETTER. Thank you.

Ms. WILLIAMS. Thank you.

Chairman WYDEN. Our next panel, Dr. Richard Marrs, M.D., Los Angeles, CA; Dr. Benjamin Younger, M.D., Birmingham, AL; Dr. Alan deCherney, M.D., New Haven, CT; and Dr. Martin Quigley of Cleveland, OH.

If you four gentlemen will come up.

Gentlemen, we welcome all of you and are very appreciative of your coming today. I think you have heard of the ground rules of the subcommittee. You gentlemen, I hope, have no objection to being sworn today.

Dr. MARRS. No.

Dr. YOUNGER. No.

Dr. DECHERNEY. No.

Dr. QUIGLEY. No.

Chairman WYDEN. Please rise and raise your right hand.

[Witnesses sworn.]

Chairman WYDEN. In the beginning, first I want to thank this panel for its assistance. We are here today because of many, many hours of work that have been done with you gentlemen and I'm very appreciative. I think this has been a very important cooperative effort between Government and the medical profession. I think it's almost a model for the kind of cooperative efforts that need to be undertaken in the future. So for that we are appreciative.

I think we will begin with you, Dr. Younger. We will make your prepared remarks part of the record in their entirety and if you could perhaps summarize your principal concerns this morning in 5 minutes or so, that would be helpful.

TESTIMONY OF J. BENJAMIN YOUNGER, M.D., PROFESSOR AND VICE CHAIRMAN, DEPARTMENT OF OBSTETRICS AND GYNECOLOGY, UNIVERSITY OF ALABAMA MEDICAL CENTER; PRESIDENT, AMERICAN FERTILITY SOCIETY, BIRMINGHAM, AL

Dr. YOUNGER. I would like to begin, Chairman Wyden, by saying that your staff and you have also spent a lot of hours and hard work on this and it has been a mutually satisfying procedure.

I am president of the American Fertility Society. I'm pleased to be here today as the subcommittee unveils the data from their survey of clinics that practice in vitro fertilization or IVF and gamete intrafallopian transfer or GIFT.

A common goal of the subcommittee and the American Fertility Society is to provide accurate information to patients. The American Fertility Society is a nonprofit organization dedicated to advancing knowledge about disorders of the reproductive system. In particular, we focus on the care of the infertile couple.

Our organization has three affiliated societies. One of these is the Society for Assisted Reproductive Technology or SART. To become a member of SART, programs must meet AFS minimal standards for IVF and must demonstrate success in producing pregnancies and deliveries.

Programs also must report their results to the IVF registry. This data is published annually in the AFS Journal Fertility and Sterility.

Since the subcommittee's June 1988 hearings, members of AFS and SART worked with Chairman Wyden and his staff to develop a questionnaire that was sent to all programs or individuals thought to be providing IVF and GIFT.

In November I sent a letter to each program informing them about the pending survey and encouraged them to respond. In all I sent out 260 letters.

This past January I sent out 96 follow-up letters to those programs that had not yet responded. 167 active programs are now responding by sending data. We identified 25 programs that are no longer preforming IVF; 32 programs or individuals have not responded. We identified some duplicate, incorrect, or inappropriate addresses; these have been eliminated.

I believe that the information released today is an accurate reflection of the current practice of IVF and GIFT in the United States. Results of the survey will be discussed by Dr. Quigley

To properly interpret results of the survey it is important to understand the natural pregnancy rate that can be expected from reproductively normal couples. Understanding this is important in having realistic expectations about the outcome of IVF and GIFT.

I would like to review the efficiency, perhaps a better term is the inefficiency, of the human reproductive system. Reproductively healthy couples desiring to conceive will do so at about the rate of 25 to 30 percent per month. This rate is derived from the use of sensitive and sophisticated tests similar to those tests used in monitoring an IVF patient.

Of naturally occurring pregnancies, approximately 30 percent, will end in miscarriage within the first 3 months. Once a pregnancy progresses beyond 3 months there is a slight chance for further pregnancy loss.

The bottom line is that in reproductively normal couples desiring to conceive, the best that can be expected is about a 20 percent chance, or one in five, that the couple will have a baby as a result of a single month's attempt to do so.

In reviewing success rates of an IVF program it is important to remember this, and to remember that IVF patients are not reproductively normal. IVF is a last result effort and provides hope for some couples otherwise unable to conceive.

Data from the 1987 IVF registry with 96 clinics reporting reveals an average take home baby rate of 11 percent per egg recovery procedure. Data from this survey under discussion today confirms that take home baby rate for 1987. This survey suggests that the take home baby rate for 1988 will be at least 13 percent.

Considering the success rates reported in previous years and comparing that to the information in this survey it is apparent that the success rate is improving. We might consider that improvement remarkable in view of the fact that there has been no Federal support for research in this area. Research dollars are important. But equally important is that standards established under research guidelines carry over into clinical practice. We believe that research is a key factor for improving results.

It has been said that half the programs performing IVF have yet to produce a live birth. Review of the data contained in this survey does not bear this out. For 1987, 28 out of 114 reporting clinics or 25 percent, had yet to produce a live birth. Of those 28 programs one had performed 55 procedures. Half of the remaining 27 had performed less than 10 procedures in a year.

In 1988 only 16 of 133 reporting clinics or 12 percent had yet to produce. Of these 16 all did less than 22 procedures in a year; 10 were doing less than 10 procedures in a year. The number of procedures being done by these programs yet to produce a live born is important, because it reveals that these programs are predominately new and small volume programs. As their experience grows most will become successful.

For GIFT programs the data is similar. This is a newer procedure and therefore the percentage of nonproducer is higher than for IVF. In 1987, 45 percent of GIFT programs had produced no babies, but this has dropped to 30 percent for 1988.

The American Fertility Society believes that there are important questions that a patient should ask when considering an IVF program. These questions not only focus on success rate but also address the qualifications and experience of personnel, the types of patients being treated in a program, available support services, and such practical matters as cost and convenience.

Patients need to know when the program started. How many babies have been born as a result of the treatment efforts of that program? Is that program a member of SART? This is one factor that can be considered in making a choice.

These questions along with other information is available in a pamphlet entitled "Questions To Ask About IVF and GIFT Programs." Copies of this pamphlet are available at no cost from the society.

Instructions are included as to how to calculate success rates. Because pregnancy is detected by very sensitive tests and because there is a natural pregnancy loss of 30 percent it is best to calculate success in terms of take home babies rather than pregnancies.

We believe that better information and better education will lead to better decisions.

In conclusion, the American Fertility Society believes that patients should have the most up to date and complete information available on infertility treatments. We plan to continue our efforts to educate our members and the public.

In addition, we believe that the data released today will also assist patients in making informed choices when selecting an IVF and GIFT program.

Thank you. I will be pleased to answer any questions.

[Dr. Younger's statement may be found in the appendix.]

Chairman WYDEN. Dr. Younger, thank you and again my thanks for your cooperation and that of the society.

Dr. Quigley, we welcome you and we will make your prepared remarks part of the record. If you could summarize that would be helpful.

TESTIMONY OF MARTIN M. QUIGLEY, M.D., PRESIDENT, SOCIETY FOR ASSISTED REPRODUCTIVE TECHNOLOGY [SART]

Dr. QUIGLEY. Thank you very much, Mr. Chairman.

This year I am serving as the president of the Society for Assisted Reproductive Technology otherwise known as SART. I am a certified reproductive endocrinologist as well as an obstetrician-gynecologist and direct the in vitro fertilization program at the Cleveland Clinic Foundation.

This morning I will be presenting and discussing the results of the survey undertaken by your subcommittee in the fall of 1988 concerning the practice of IVF and GIFT in the United States in 1987 and 1988. Before I get into the data I would like to briefly describe exactly what these two procedures are and which patients should be treated by these two procedures.

IVF involves several major steps. First, drug treatment in order to produce the simultaneous development of several fertilizable eggs instead of the one that normally develops in a woman's menstrual cycle.

Second, egg recovery usually performed today using ultrasound guidance to locate the eggs and removal of these eggs through the top of the vagina with a minor surgical procedure.

Third, addition of the husband's sperm and documentation of fertilization.

Finally, placement of the early preembryos in the wife's uterus.

Today, IVF has recommended treatment for couples with otherwise untreatable infertility. This includes couples with tubal factors; male factor; endometriosis; as well as unexplained infertility.

It must be emphasized, however, that IVF is a treatment of last resort and is not an appropriate choice or recommendation when other infertility options are available.

GIFT in many ways is analogous in vitro fertilization but does have important differences. The principal difference is, with GIFT instead of allowing fertilization to occur in the laboratory eggs and sperm are mixed and immediately returned to the wife's fallopian tube where natural reproduction, natural fertilization occurs.

Thus, women to be treated with GIFT must have at least one normally functioning fallopian tube. Most GIFT procedures are done with egg collection performed by means of laparoscopy. Laparoscopy is a surgical procedure which a lighted telescope is used to visualize a woman's ovaries. During the laparoscopic procedure eggs are recovered, the husband's sperm is added, and the egg-sperm mixture is immediately returned to the wife's fallopian tubes.

Patients to be treated by GIFT include patients with limited endometriosis and normal pelvic anatomy, unexplained infertility or male factors.

The advantages of GIFT include a higher pregnancy rate than is usually achieved with in vitro fertilization. The disadvantages include the fact that general anesthesia and laparoscopy are required for egg recovery. That unless pregnancy occurs the couple receives no information as to whether the wife's eggs were fertilized by the husband's sperm.

In addition, not all infertile couples can be treated by GIFT. In other words, the wife must have normally functioning fallopian tubes. Similar to IVF, GIFT is only appropriate for couples in whom all conventional infertility treatments have been tried unsuccessfully.

As mentioned many times this morning the only statistic that really matters to patients is the birth of a live child. Therefore, for the purposes of your committee's survey, since the major discomfort, risk, and expense is involved with the egg recovery procedure the data will be presented in terms of live births per attempted egg recovery procedure as much as possible. Obviously, to have the most current data the 1988 results by necessity include a combination of live births and pregnancies in progress.

In any case, the method of analysis and reporting is consistent for all programs allowing meaningful comparisons to be possible between different programs and giving information that can allow patients to make a more informed choice when undertaking in vitro fertilization and GIFT treatments.

As of Tuesday of this week, March 7, the data from 139 clinics was available to me. As a general statement, virtually all reporting clinics conducted IVF cycles with about 85 percent also doing GIFT. With a couple of exceptions most clinics did far more IVF procedures than GIFT procedures.

Now for the ease of following the numbers you may want to consult the two tables at the end of my written testimony. In 1987 there were 11,588 IVF stimulation cycles. In 24 percent of these cycles no attempt was made at egg recovery. In 8,782 attempts, egg recovery were made of which 87 percent culminated in an embryo transfer procedure. There were 1,019 live born children in 1987 resulting from GIFT, a rate of 11.6 percent for egg recovery procedure.

In 1988 there were 13,840 stimulation cycles and in 20 percent no attempt of egg recovery was made, resulting in 11,032 egg recovery procedures of which 88 percent resulted in embryos being placed in the uterus. 577 live born children resulted and 1,148 clinical pregnancies were listed as ongoing at the time of completion of the questionnaire.

Together, the live born plus continuing pregnancies result in a 15.6 percent rate per egg recovery procedure.

As far as GIFT, and this is table two, there were 3,347 stimulation cycles in 1987 of which 27 percent were terminated before egg recovery. 2,461 egg recovery procedures were performed which resulted in 351 live born children, a rate of 13.3 percent live birth for egg recovery procedure.

In 1988, 3,937 stimulation cycles were begun of which 20 percent did not result in attempted egg recovery. 2,976 egg recovery procedures were performed resulting in 342 live born children and 513 continuing pregnancies. Live births plus continuing pregnancies represent 28.7 percent of the egg recovery cycles.

Now in the fall of 1986 a national IVF registry was developed as a joint project of SART, the American Fertility Society, and Medical Research International. Dr. Stewart Hartz from Medical Research Intentional will be discussing the more detail later in this hearing.

However, I will be using some of the published registry data to help place the subcommittee's survey results and perspective. If we use the same reporting system used in the subcommittee's survey to the published registry data the live birth per egg recovery procedure rates from the registry data were 8.9 percent in 1985; 9.2 percent in 1986; and in 1987 when all the cycle data was available 11.4 percent of the retrieval cycles result in a live born child. Quite an excellent correspondence with the data and the subcommittee survey.

Now, one of the criteria for membership in SART is performance of at least 40 IVF stimulation cycles per year. We felt that under normal circumstances this was the minimum number of cycles per year that would allow a clinic to maintain the necessary expertise, especially in the embryo laboratory.

When the 1987 data from the subcommittee's survey are examined, and I took 1987 because all the live births for 1987 should be reported, there were 72 clinics that had initiated at least 40 stimulation cycles. Of these 72 clinics—97.2 percent—reported at least one live birth in 1987. Of the 70 clinics with live births the minimum live birth rate for egg collection procedure was 1.5 percent and the maximum was 25.3 percent. Three clinics reported rates over 20 percent and 16 reported rates over 15 percent. Conversely, 9 programs had rates less than 5 percent and 20 had rates less than 8 percent, this is excluding the 2 programs with no live births. The remaining 34 clinics—which is slightly over half—had rates between 8 and 15 percent. These figures are illustrated in the graph on the very last page of my written testimony.

When the differences in patient populations are taken into account, as should be available in the future, I believe these data will show a reasonable amount of consistency from clinic to clinic.

Now, there are concerns about the accuracy of the data. The questionnaires were distributed in November 1988. Some questionnaires were returned immediately and I have been told some didn't arrive until this morning. Thus, some questionnaires will contain only partial data for 1988, some will contain complete year data for 1988.

The true live birth rate calculated for 1987 is actually probably higher than the data allows. The reason for that is, there were more cycles done in 1987 than 1986. Most of the births that occurred in 1987 were a result of 1986 treatments. Thus, you are dividing 1987 pregnancies by a larger number of treatment cycles.

The 1988 data has an additional inaccuracy in addition to the increase in number of cycles and that is, there is an uncertain proportion of the continuing pregnancies that will terminate in a spontaneous miscarriage. For calculation purposes I have taken the worse case scenario and assumed about a 30 percent pregnancy loss rate of those reported as continuing for 1988.

For several reasons infertility and treatment have become more important in recent years. Advances in infertility practice have led to the development of treatment for most of the causes of infertility. For the fraction of infertile couples for whom infertility treatment have been unsuccessful or for whom there is no conventional therapy IVF and GIFT are now more widely available.

Overall, IVF and GIFT are becoming more widely applied in the United States. Using the previously published data from the registry as well as subcommittee survey data there has been a progressive increase in the IVF live birth rate for egg collection procedure from 8.9 percent in 1985, to 9.2 percent in 1986, to 11.6 percent in 1987, and finally, an estimated 12.5 percent in 1988 where I make allowances for 30 percent pregnancy loss rate.

As a general statement, the likelihood of a live born child for egg recovery procedure is greater with GIFT than IVF, although it was mentioned earlier not all patients treatable by IVF are treatable by GIFT.

Specifically the 1988 data suggests that GIFT live birth rates for treatment cycle are about double that achieved with IVF.

Chairman Wyden, staff members, I thank you very much for the opportunity to have commented on the result of your survey.

[Dr. Quigley's statement may be found in the appendix.]

Chairman WYDEN. Dr. Quigley, thank you very much.

Why don't we go next to Dr. deCherney.

TESTIMONY OF ALAN H. DECHERNEY, M.D., PROFESSOR OF OBSTETRICS/GYNECOLOGY, YALE UNIVERSITY SCHOOL OF MEDICINE; PAST PRESIDENT OF SART; MEMBER OF BOARD OF DIRECTORS OF AMERICAN FERTILITY SOCIETY, NEW HAVEN, CT

Dr. DECHERNEY. Chairman Wyden, I'm Alan deCherney, professor of OB/GYN at Yale University School of Medicine. I'm the immediate past president of SART and I serve on the board of directors of the American Fertility Society.

I would like to address the topic of patient exploitation and disillusionment in regard to physicians who practice infertility medicine.

There has been a tremendous growth in the number of doctors practicing infertility medicine in the past few years. This is due to a number of factors including increased patient need and demand, malpractice crisis, development of new commercial technology, and the entrance of for-profit organizations into the field in greater numbers.

The malpractice crisis has had a tremendous impact on the practice of obstetrics and gynecology. Obstetrics has become an area of threat to the physician and therefore they have changed the saver means of practice.

The practice of infertility medicine represents an excellent example. If we look at outcome in general, infertility overall has a cure rate of approximately 60 percent. Therefore it is extremely difficult to monitor an individual doctor's success rates since the failure rates are so high, that is, 40 percent. This is also dependent upon the etiology of the infertility as well. In vitro fertilization has a lower success rate than reversal of tubal ligation, as an example.

The development of new technologies has in the past 10 years caused a tremendous change. As we are now able to do many things that we were not able to do in the past. Doctors now have the opportunity to manipulate the biologic system in a number of ways, some of these are obviously beneficial for patients and some can be used to detrimental effect.

The entrance of for-profit organizations into medicine and the conversion of medicine, at least philosophically into a business has caused new priorities in the practice of medicine. Certainly fiscal responsibility is important. But it also opens doors for economic exploitation. Exploitation is defined as the unjust or improper use of another person for one's own profit or advantage.

If substandard or unnecessary medical care is rendered to the infertile couple, exploitation has occurred. How can exploitation occur?

One example of exploitation is inappropriate use of credentials. Taking a 2-day course in IVF and calling yourself an IVF expert is an example of misuse of the new reproductive technologies. Promising things that can't be accomplished is another. Truth in advertising is an area with potential for exploitation, and in fact is the essence of the hearing today.

Infertility patients are exceptionally vulnerable to exploitation. The practice of infertility is safe. No one dies. As mentioned, success rates are not high; therefore failure rates are difficult to assess.

Most importantly, though, patients are desperate to have children and will go to any length to accomplish this goal.

There are a number of built-in mechanisms to protect patients. One is the credentialing process. The American Board of OB/GYN provides superior credentialing. Physicians take written and oral exams to attest to their competence in obstetrics and gynecology and reproductive endocrinology as well.

The American Fertility Society through SART and other affiliated societies provide surveillance and sets practice and ethical standards. The question that arises is outside monitoring important and necessary.

Certainly I endorse regulation of laboratories. There is a well set up State by State mechanism for this and our IVF gamete laboratories should come under this same scrutiny.

The larger question then is, should some form of regulation of clinical practice occur; determining what credentials people need to practice infertility medicine; monitoring success and failure rates; and establishing ethical and quality assurance issues.

The British have set up a voluntary licensing authority made up of physicians and other members of society to inspect and scrutinize IVF centers that perform the new reproductive technologies. This is a highly successful process and perhaps can provide a model for us in this country.

In 1987 only 28 out of 98, 38 percent of centers, had no success and only three of those centers did more than 30 cycles.

In 1988 only 12 of 119 centers, 10 percent, had zero success rates and only 5 of these did more than 10 cycles. Contradicting the premise that 50 percent of centers performing IVF had delivery of a live baby.

In regard to the data collected by the Wyden subcommittee the most important aspect of this other than the data itself is the ability for the individual centers to qualify and explain their data. Although this report has the potential for much good it also has the potential for some harm in that centers that select their patients to be successful will on paper look better than other groups.

The centers that do women over the age of 40 or include males with low sperm counts or will do more than two cycles in patients will definitely have lower success rates. We would hate to disenfranchise those patients from care who are—whose chances of success are somewhat skewed.

In summary, some exploitation of patients by physicians in the field of infertility medicine does exist. The magnitude of this is not known. My estimate is that it is proportionately quite small. The dissemination of data is helpful, but also has the potential for confusion. Physicians must have the ability to qualify their data when counseling individual patients.

Last, I support the IVF registry as it exists under the aegis of the American Fertility Society, SART, and Medical Research International. This provides a valuable tool for patient and physicians alike to evaluate success rate.

I hope that this collection and dissemination of data will lead to improved doctor/patient relationships and not favor what is already in some instances an adversarial one. Thank you for giving me an opportunity to speak.

[Dr. deCherney's statement may be found in the appendix.]

Chairman Wyden. Dr. deCherney, thank you.

Mr. Marrs.

TESTIMONY OF RICHARD P. MARRS, M.D., DIRECTOR, INSTITUTE FOR REPRODUCTIVE RESEARCH, HOSPITAL OF THE GOOD SAMARITAN, LOS ANGELES, CA

Dr. Marrs. Thank you, Mr. Wyden, I appreciate the opportunity to speak to you and the members of your subcommittee.

I would also like to thank you and your staff for continuing to work, to increase public awareness, and improve patient knowledge as to the possible pitfalls with the new reproductive technologies or with the providers of those services.

It is not my purpose today to discuss how the system has failed. Instead, I would like to offer some discussion to change the system so that it may provide the patient with emotional and financial support.

A hotly debated issue of outcome reporting is still a concern to me and you have heard the other speakers on this panel discuss outcome. I think the patient population is still concerned about outcome reporting.

The questionnaires that your committee received reflect the outcome statistics reporting on an individual center basis and that is the first time that this type of reporting has been available to the patient population. About 121 centers or more at this date have provided information.

As Dr. deCherney said, in 1987, 28 of those centers reported no pregnancies. That accounted for 357 egg recovery cycles of in vitro fertilization. This constituted 22 percent of the centers reporting having no pregnancy outcome. It accounted for 2.5 percent of the cycles that were performed. If you consider an average cost of $5,000 per patient cycle that accounts for $1.8 million in patient cost.

Of the centers that did not respond to your request for information how much of the cycle percentage do they represent and how many patient dollars were spent in those centers that have yet to achieve a pregnancy?

Even though I feel that this report is important, how reliable is it? Is the anonymous reporting of the IVF registry a more honest representation of outcome? I don't know.

However, I do think that for any of this data to be validated and acceptable we really need an independent auditing process to look at this data as it is published.

Of equal concern is the obvious absence of all the centers that were asked to respond. There are some well-recognized centers in this group that didn't make their data available to this report.

Are these individuals implying by their refusal that they can play by a different set of rules? Do some centers feel immune to the review process or standardization of policy in these areas? If so, I think a dangerous precedent is being established by accepting this silence.

The information that has been available to the consumer prior to this report has been scarce and often misleading. This is not surprising when a review of the medical literature in this field is undertaken.

I feel very strongly that identification of live births produced per procedure performed is the only marker that the patients will utilize in their decision-making. To discuss preclinic abortion, biochemical pregnancy rates, and the like will only confuse the issues. This success or failure rate needs to be factored by the number of stimulation cycles and the number of patients undergoing an egg recovery procedure.

Since the cost of stimulation of ovarian inducement for multiple follicle development is rising, the cost of drugs is continuing to escalate. A failed stimulation attempt may cost the patient as much as 30 to 40 percent of what the overall cost of the completed cycle would cost. Thus, the reporting needs to be viewed according to the number of stimulation cycles as well as patients that underwent entire procedures.

I recently had cause to review the last several years of scientific publication in the areas of in vitro fertilization and found to my surprise that even with my level of sophistication it was difficult to extrapolate live birth rates and outcomes of live birth rates from a large percentage of these published reports.

If this type of information is being accepted by peer review journals how can we expect the patient population to receive a clear concise data upon which they can base a decision concerning their treatment options?

The honest discussion of factual outcome will go a long way in decreasing emotional stress in this very vulnerable population of patient.

Another areas of concern and stress to the patient group is the increasing financial burden they incur. Whether you look at the cost of basic testing or evaluation or that of the assisted reproductive technologies, the cost to the patient is escalating rapidly.

Along with the fact that in most States infertility evaluation treatment is a noncovered item by health insurance, the infertile couple bears the entire expense. With escalating drug and hospital costs the ability to have a child, if infertile, is rapidly becoming available only to couples with financial means.

After your hearing in June 1988 much progress has been made toward improving the quality of care and the assurance of that quality. I feel strongly, however, that the voluntary reporting or unaudited reporting accomplished only part of the goal.

It appears from our efforts through SART and the American Fertility Society and other national organizations that we have limited, if any, ability to regulate or standardize the care in this area. I strongly feel, therefore, that there needs to be a multidisciplined approach to improve consumer protection.

With your permission I would like to suggest the following model:

Laboratories providing and performing tests or evaluations of oocyte or gamete function should be licensed. Just like any other diagnostic laboratory on a State to State basis.

Laboratories that perform GIFT, IVF, ZIFT, TET, all these new reproductive processes that are coming down the pike, embryo freezing, anything that we are doing now or in the future should also be licensed. Those laboratories need to be reviewed. The State to State licensing may be the most appropriate model.

Organizations that might offer oversight in this process would be the College of American Pathologists, American Association of Tissue Banks, and others. These organizations could work in conjunction with an independent board of expert consultants to establish guidelines and standards.

I also think a national effort should be undertaken to mandate coverage of infertility evaluation and treatment by third party payers. The cost would be borne by the individual insured in the form of premium writers with those needing coverage. Insurance carriers in turn can request a certification of facilities to determine the levels of reimbursement, thus, improving the level of quality assurance to the patient population.

The final area of oversight could come from an independent licensing board. The purpose of this board would be to sight visit and review clinical, laboratory, physical facilities, personnel, and patient reporting on a year-to-year basis.

This independent board could be made up of clinicians, scientists, statisticians, and ethicists. The board, at the request of a center would evaluate that center and license it, certify it for a definitive period of time. The expense and other items could be and should be borne by the center. This accreditation list would then be public information. It would be available to the patients and it would be again a higher level of accreditation than what we have today.

Also, centers that don't meet accreditation guidelines could form a relationship with an accredited center and therefore you can have a regionalization or establish a networking of smaller and larger centers which again would improve efficiency.

I don't know whether these approaches are possible or feasible on a State or national level. However, I do think these are the issues that we must discuss. The patients we care for are extremely vulnerable and susceptible to unscrupulous practices. Even though that occurs in a very small percentage of cases, the system should be designed to exclude even the slightest possibility of emotional or financial manipulation.

We all must maintain the ability as physicians to treat our patients to the best of our abilities. But we also must be able to withstand peer or governmental review as any other professional.

Again, I thank you for your energy and interest in these sensitive issues of human reproductive health care. Thank you.

[Dr. Marr's statement may be found in the appendix.]

Chairman WYDEN. Dr. Marrs, thank you for your second appearance before our subcommittee. You have been just very, very helpful over these last few months, as have all of you. I want to ask some questions to go into your testimony in detail.

Let me first say, I said in my opening statement that I think we need to understand what this data can do and what it cannot do. I think all of you have highlighted that. There are some very obvious kinds of considerations. That is, if a clinic is to take less difficult cases, it will have a higher success rate. If it takes more difficult cases, that just by nature of the difficulty of those cases, it will have lower success rates. I would just point out that that is why, as we publish this data, we have asked the clinics to include explanatory material because we believe that will give them, in their own words, in an unfiltered way, an opportunity to address those kinds of issues. I think you make an important point and one that I share.

Now, let me see if I can ask some simple questions, first, that will help to frame the debate for Congress in the future. I am going to introduce legislation to regulate the embryo labs. It will essentially subject them to the same kinds of requirements as other labs—the labs doing blood tests or cholesterol tests or things of that nature that are subject to certification, inspection, and enforcement and those kind of requirements in the statute. Would all of you be in support of that legislation, Dr. Younger?

Dr. YOUNGER. I think that speaking as the president of the society, that concept is certainly not strange to us. We have never had a request before this fall to really interact with Congress. I think we responded positively in coming to work with you immediately after the board of directors met. I think, given the opportunity to review that legislation and have input into it, I think we would end up being very happy to endorse it.

Chairman WYDEN. Any of our other witnesses? Dr. Quigley?

Dr. QUIGLEY. I would just like to add one thing. Obviously, I support the concept of Government supervision, regulation of embryo labs like all other clinical labs. I do want to make one point. The technologists working in these laboratories have often chosen a different pathway to get where they are. In other words, because of the way in vitro fertilization has developed in the last decade, it started out primarily as a research, reproductive biology research effort, and there were many entirely competent—in fact, superb technicians in these laboratories who do not meet the criteria to allow them to work in clinical labs. There has to be some recognition of the special pathway the current workers have achieved to get where they are.

Chairman WYDEN. Dr. Marrs or Dr. deCherney?

Dr. DECHERNEY. I have no problem with that.

Chairman WYDEN. There is no logical reason in the view of all four of you, then why embryo labs should not essentially be subjected to the same requirements as other labs?

Dr. DECHERNEY. In fact, I think it is a welcome addition to what we do.

Chairman WYDEN. The second question I wanted to ask dealt with the question of credentials and the like. Is it correct that at present any doctor, any doctor who is licensed in this country, can hold themselves out as a fertility specialist?

Dr. YOUNGER. That is correct. As Dr. deCherney indicated, malpractice has had a significant influence on our specialty. Particularly, I think amongst older doctors in my own area, we are seeing them change the letterhead on their stationery from obstetrics and gynecology to gynecology and infertility. It is predominantly an office-based practice rather than a hospital-based practice. Since residencies in obstetrics and gynecology are required to have a certain minimum amount of training in the diagnosis and management of infertility, people put this on their letterhead.

Dr. DECHERNEY. Any doctor that is licensed in this country is licensed to do anything. I can do neurosurgery in my kitchen if I have a mind to.

Chairman WYDEN. I understand that and the question, of course, is important as it relates to the promotion of these services. That is really my next question. That is, are there any standards that have been adopted by the American Fertility Society, Dr. Younger, with respect to the advertising and promotion of infertility services?

Dr. YOUNGER. There are no standards that I know of that really relate to advertising in many medical specialties or medical societies and certain AFS is no exception.

I would like to point out that I believe that editorially, our society has been very responsible. In 1985, Mike Soles from your neighboring State, the University of Washington, in the Editor's Corner of Fertility and Sterility addressed the question of "Let's be honest in reporting IVF results."

In my own State, a younger colleague, at the University of Alabama, Dick Blackwell, in 1987, again addressed the issue, "Are we exploiting infertile couples?" Dr. deCherney here and Mike Soles that I mentioned were coauthors on that article. Much of that article really addressed the issue of truth in advertising. I think it is a significant problem. It comes about because we are in, quote: "The business of medicine." There is for-profit corporations. There are stockholding corporations that promote IVF. They expect a return. They advertise things that we in university settings never dreamed of.

Chairman WYDEN. Has AFS taken any action against those that they have seen misrepresenting or exaggerating in their advertising and promotional material?

Dr. YOUNGER. Since we are predominantly an educational organization, we are really not set up to take action. We are an open society where membership implies interest and not expertise.

In certain instances, maybe Dr. Quigley can speak to this, but individuals have been asked to verify results of an application. Those results were verified. So, an inquiry has been made and no negative action has been taken.

Chairman WYDEN. Dr. deCherney, what about through SART? Has SART taken action against those who engage in some of the advertising and misrepresentation that you and our other witnesses have talked about?

Dr. DECHERNEY. SART has not done that because it is not part of the way that we have set up our society in that we look for a more tangible criteria, as Dr. Quigley mentioned, 40 cycles per year.

There is another affiliated society in the American Fertility Society, the Society of Reproductive Surgeons, in which that is taken into account, that people's credentials, people's ethical practice. But in SART, itself, ethical practice is not taken into consideration.

Chairman WYDEN. Let me ask you, Dr. Younger, and maybe your associates as well. Do you think that is the next step, that SART and AFS and professional groups in this area adopt some standards with respect to advertising and promotion? I note that you all have written articles, very thoughtful articles that I quote constantly. I wonder if as we look to the next steps with this question, whether adopting some standards in advertising and promotion is one of those next steps?

Dr. YOUNGER. That question has never been asked of the board, but I am sure that it will, as a result of the type of hearing we have today, will come under discussion in the future. Again, our emphasis has been educational and as we heard to begin with this morning, it sounds like there are a number of doctors out there that could stand a little education about infertility and if we restrict our membership, then we would be restricting education opportunities for them. That is something we do not want to do.

Chairman WYDEN. Dr. Quigley?

Dr. QUIGLEY. Basically, SART was in the discussional phases in about 1984 to early 1985. When the organization was conceived, it was not thought to be—in fact, it was thought to be as far removed from any sort of credentialing or supervisory position as you can imagine. It was a forum for education, for scientific exchange, for collection of scientific registry data.

We find ourselves, unfortunately, at least from the way we set up the society of being forced into a credentialing type situation to where insurance companies are beginning to consider SART membership as a criteria for reimbursement or not. I am not sure that that is the role for our society.

I think if you look at the example of the certifying specialty boards, you will find that these boards are to some degree, at least as much as possible, removed from the people that are being examined. They are composed of representatives from many societies: The American Board OB/GYN has representatives from the Association of Professors of Gynecology and Obstetrics, the American Medical Association, the American College and so on. I think it might be better to set up a system analogous to the British system where there is a totally independent supervisory board who can look into the matters of truth in advertising, who can do credentialing, who can do site visiting, where you get not only the people in competition with the people being investigated doing the investigating, but scientists, statisticians, totally uninvolved professionals who can assist in this whole supervisory process.

Chairman **Wyden**. Are you saying that the Government should set up some kind of oversight board over the field?

Dr. **Quigley**. Definitely not. But I think that———

Chairman **Wyden**. Who would run it? Who would pay for it? You used the words, independent oversight. Around here, that always connotes certain things such as the taxpayers paying for someone who is not in the field to do it. Who would you propose run such an independent oversight board?

Dr. **Quigley**. I take the board model. When people have completed their residency and go through the board certification process, it costs $500 to $1,000 per set of examinations and a candidate is required to go to Chicago and be examined.

Turn that thing around and the center that is going to be certified, going to be examined, will pay a fee of $5,000 plus the travel expenses of the five-man committee to come in and spend 2 days there. Something like that. I think working together with the American College OB/GYN, the American Fertility Society, and SART, we could come up with some sort of an independent body.

Chairman **Wyden**. I would certainly want to talk with you some more about that. But just from the seat of my pants, if someone pays for a test and those doing the testing are part of an oversight body, that does not strike me as bringing the kind of independence and outside oversight that would be my approach to it. I would like to hear some more about it and I realize you did not come today to talk about this in any detail.

Dr. **deCherney**. There is a mechanism for this in that we all have State medical societies that are set up to monitor. We are talking about one isolated aspect of medicine, the infertility patients. Monitoring this kind of behavior is handled by State medical societies. The mechanism and hierarchy is already in place.

Chairman **Wyden**. How do you think those State medical societies are doing, Dr. Marrs?

Dr. **Marrs**. I think the State Medical Society in Virginia in the Jacobson case is a good example of how it does not work. I do not think—I think you have to have, if we are talking about an independent board that will provide oversight, it has to be a multidisciplinary approach. It cannot be just the practitioners of medicine looking over their peers.

I think that is where we have to look to Government, State or Federal, to provide an interaction there. Yes; it has to be made up of scientists and clinicians because Government does not know the process. But it cannot be one without the other.

Dr. YOUNGER. Mr. Wyden, I would like to make one comment concerning the truth in advertising is that, first off, we live in a day and age where there is tremendous emphasis on the health care of women from the marketing point of view. Every town you visit and you look in the local magazine that is in the hotel room, there is some advertisement there for women's health care services. Certainly, one of the most visible of these is the high tech reproductive health services such as IVF.

Now, every time I have had the opportunity to try to look at somebody's advertising and their data, what we have found is that they are actually not lying. They just take data and put it into the framework that is most favorable for attracting patients. They end up starting like an IVF for a certain period of time. We all recognize that there are hot periods and cold periods. So, they just report on one of those hot periods. They phrase it in language that is absolutely correct. But it is the ethical considerations of doing that that really concern, I think, the American Fertility Society.

Chairman WYDEN. I think that puts it very well, Doctor. I would just say by way of the next step, I would hope that your group in conjunction with SART and others look to set up some guidelines with respect to ethical practices in advertising. I think that we have just countless ads that have arrived at our subcommittee office and many of them really, if they are not totally misleading, clearly do not present the whole picture.

I think that if this continues, there will be a push for Government regulation to control this. I would hope that you would pursue this in a voluntary way and move very vigorously in that regard.

Now, one other area I wanted to ask you about is the problem of defining success and what appears to be the lack of a common definition for a success. What is your assessment of this problem and why could we not come up with some common definitions of success as well and use that as part of a program to get information to citizens?

Dr. YOUNGER. I think you have heard all of us say that success, probably the best way to express it in its terms of babies per egg recovery procedure. That particular formula could apply to either IVF or GIFT. One of the real problems with that, though, is that it is going to take a program a couple of years to really establish a track record. I think if you will look in the little pamphlet that we attached to the testimony it goes through the various formulas for calculating success and it does emphasize the take home baby rate.

Chairman WYDEN. Why not start with stimulation cycles if you are going to begin to define this area?

Dr. YOUNGER. Do you want to answer that, Martin?

Dr. QUIGLEY. Again, if you look through the data, it was fairly consistent that around 20 to 25 percent of stimulation cycles, be it either GIFT or IVF, terminated before an attempt at egg recovery was made.

What we are trying to do today is maximize the chance that a couple will have a baby to take home at the minimum expense, risk, discomfort, if you want. The stimulation cycle, even though it is getting more expensive as the drugs become more expensive, is still but a small fraction of the cost of egg recovery procedure itself. So, our tendency today is only to take people to egg recovery who we think have a good chance of becoming pregnant. So, we would rather terminate the cycle rather than be forced to carry it on.

If the criteria that is used as a benchmark for success is stimulation cycle started, then we would be forced, if it becomes part of insurance reimbursement or credentialing or what not, would be forced to carry patients through the whole system to try to eke out a few more pregnancies.

In other words, once we had made the decision to start a stimulation, we would be forced to do things that were against our better judgment.

Chairman WYDEN. Dr. Marrs, I think you have strong views on this question of what would constitute a success. I believe your views are possibly a little bit different than the comments just made.

Dr. MARRS. Several years ago, I made a strong statement about the fact that live births outcome reporting would best be determined by looking at the denominators being the egg recovery procedure. At that time, people were using embryo transfer procedures as the denominator. Also, at that time, the average cost for a stimulation cycle that may fail was $500 or $600.

Today, if we fail to stimulate properly and drop a cycle, it is somewhere in the range of close to $2,000 with the use of agonists, high level, high doses of gondatropins, laboratory monitoring, the ultrasound monitoring that goes into that. It is not an insignificant amount of cost.

I think, certainly from a live birth perspective you need to talk about both. You cannot say, "We are only going to talk to you about births per stimulation cycle or births per egg recovery cycles," because when the patient comes into your facility, you have to explain to her her financial burden. I mean these patients are looking at $8,000, $10,000, $12,000, $20,000 for a couple of cycles of IVF. If they have three cycles that fail to stimulate, they could be spending $6,000 or $7,000 and never get a chance at pregnancy. So, I think we have to look at both markers. Not so much to say that the clinical outcome is best served by looking at stimulation cycles, but when you look at the patient as a whole, and look at her events that she is facing: financial, emotional, and physical. We talk to them about both.

Chairman WYDEN. Dr. Younger, just one other question for you. What implications should one make about the 32 clinics who did not respond to this survey? We wrote them, contacted them repeatedly, and the Fertility Society wrote and contacted them repeatedly as well. What implications would you derive from their nonparticipation?

Dr. YOUNGER. I can only relate to you what contact I have had from some of the nonresponders. There are a group of programs on that list of nonresponders and, perhaps, Dr. Quigley can go through them with you, that probably do not exist any more, are not active or have combined with some other program. Why they did not respond, particularly, to my second letter that clearly said let your office know if they were not responding, I have no idea.

There are a group of individuals that resent this as an unnecessary intrusion of Government into private business. There are—I can recall one conversation that an individual called me and he said:

> You know, my GIFT program, we are getting a 25 percent success rate, but there is a program here in town that is advertising a 60 percent success rate, and if I report that and people will compare them, and I will not get any patient referrals.

My comment back to that individual was, "Well, golly, it sounds like your success rate is as good as anybody else's." I have had the opportunity to look at the final data and nobody is reporting a 60 percent success rate.

I think that gets into the lap of advertising. There may be a few programs in there that because they are not producing good results did not want to respond. So, I think it is a hodgepodge in those groups that have not responded.

Chairman WYDEN. But I gather from your comments, then, that this is becoming a pretty competitive business and that somehow the notion of classic medicine may not apply completely in this field. It is a growth industry and that this is going to really be, you know, elbows out, competitive business in the future. Is that right?

Dr. YOUNGER. It appears to me that one of the things that I have been interested in is seeing that there are indeed a group of stable programs that we have all known about for years. But there is always somebody else that is getting ready to open a new program.

I talked to an individual from California who said, "Although my data is reported in one of the programs here included in the survey, I am thinking about pulling out and opening my own."

So, yes, there are people that are considering opening new programs. Some of the people I know do not meet the minimal standards as published by AFS. I will point out that it is on the agenda to update those standards this year. They were done in 1984. It is 5 years. We want to update them. But there are individuals, I think, that are going to start programs because it sounds easy.

Chairman WYDEN. With respect to those standards for AFS, which you have described them as minimal, and that they have to be upgraded. If people do not comply, there is really not much you can do.

Dr. YOUNGER. The only thing that we can do as a society if they do not meet the minimal standards, then they cannot become a member of SART. As was said, whether or not a program is a member of SART might be one factor that patients want to consider when choosing an IVF program.

Chairman WYDEN. But there is no restriction on their right to go out and practice even if they do not meet the most minimal standards.

Dr. YOUNGER. That is correct.

Dr. **deCherney**. But you are not trying to imply that this is the most competitive aspect of medicine today, are you?

Chairman **Wyden**. I think I am asking the questions.

Dr. **deCherney**. I will let that stand as a statement even though it came out as a question.

Chairman **Wyden**. I think it is quite clear, both from our previous hearing and other ones, that this is one of the growth fields of modern medicine. No one is suggesting that perhaps this is going to be more lucrative than any other field. But there is no question in my view that this is a very lucrative field of medicine and my sense is that those who do not engage in big time marketing, those who are not going to go out and do very aggressive advertising are going to find it very difficult to compete in this field. Dr. Younger's last comments certainly reflect that because he said that someone with a very high success rate or what sounded to be a very high success rate did not want to cooperate with the subcommittee's survey after requests from both the subcommittee and the society simply because someone down the road might have a slightly higher rate. That certainly gives us grounds for being concerned about where we are going in the advertising area and, frankly, supports my suggestion today that we move very, very quickly to come up with some voluntary guidelines at the least on advertising and promotion and what is told consumers.

Dr. **Younger**. I think that for the actual physicians doing IVF, although it may be seemingly costly as an individual procedure, that there is not a great deal of profit margin. In many of the hospitals or many of the programs that advertise very aggressively, they have hospital backing, it is into big women's centers, women's groups. It is all tied to the advertising that goes along with the health care of women in this country and the fact that marketing surveys show that where mamma gets her care that is where the rest of the family will get their care. They underwrite some of these programs because of the high visibility that an IVF program would give that particular women's health care center.

Chairman **Wyden**. I would only say, Dr. Younger, we did not inquire on our survey about profit margins and the like, but I think it is worth noting that practitioners are not tripping over themselves to get into this field for nothing. They clearly recognize that this is a growth field and we may need to get some additional information on some of these financial issues. But it is unquestionably a growth field. In my view, it is going to become a field that is going to grow even more dramatically in the years ahead because couples, according to everything we know today, are going to continue to wait until later in life to try to conceive. The problem of sexually transmitted diseases is going to certainly be a factor in this area. I see no information at all that does not make this a growth industry by anybody's calculation.

The only other question that I had for you, Dr. Younger, is the question of really where we go from here now that we have taken this first step. Do you think that there should be a follow up to this, that there should be required, the reporting of this kind of data by clinics either through AFS or SART or through some other program? Where do we go from here?

Dr. **Younger**. I think it would be very difficult for AFS and SART to have any influence on people that are really not members of those two organizations. Therefore, if there is required reporting, it would have to come through some other avenue.

Chairman **Wyden**. Do you think the Federal Government should get into this through the Department of Health and Human Services?

Dr. **Younger**. I think it has either got to be Government or an independent board and I realize that you and Dr. deCherney are going to discuss the concept of regulatory boards away from the microphone when more time permits.

Chairman **Wyden**. I think it is going to be necessary to get some sort of ongoing followup. The debate will be, as it so often is, whether this could be done in the private sector or through a process that involves a role for Government. We have been able to do this, I think, in a very satisfactory way because of the patience and the cooperation of the Fertility Society. But, clearly, with the field changing so dramatically, we are going to need to have a process on an ongoing basis to get this kind of information out. We will want to work with you as we look to approaches either outside the Government or through the Department of Health and Human Services.

Dr. **deCherney**. One way to accomplish both goals or both sectors' goals is for the Government to support research in this field because that would be a way that there is some Government scrutiny, but at a different level than scrutinizing the business aspects of medicine.

Chairman **Wyden**. Dr. deCherney, I think as you, Dr. Younger, and I have talked about, I am going to be very active this session to try to promote additional funds for research. It is my view that we have been incredibly shortsighted over the last 8 years in shortchanging research. I think we are paying daily because of that shortsightedness. I think you will find very strong bipartisan support in this session for additional funds for research.

But the debate about research is different, it seems to me, than this question of getting out the data. The question of getting out the data on an ongoing basis requires that we make a decision about whether it can be done in the private sector through voluntary groups or whether Government should do it. So, I only want to say that while we support and support strongly your efforts for additional funds for research, this question about consumers' access to current objective data is quite another question and presents us with other problems.

Dr. Younger, did you want to add anything?

Dr. **Younger**. No; thank you. It has been a pleasure working with you. I presume we will continue our efforts.

Chairman **Wyden**. You have been very, very helpful and we are going to continue this. I view this more as a start than an end.

Let me ask just a couple of other questions for Dr. Quigley and Dr. Marrs.

Doctor, you said that it is mandatory that both partners be thoroughly evaluated to maximize the chances of successfully establishing a pregnancy. But we have heard again earlier this morning from one of our witnesses, a woman, who believed that she was not properly evaluated and, in fact, essentially misevaluated. In your view, how often does this happen? Is this a rare case? How often do you think it happens?

Dr. QUIGLEY. Unfortunately I don't think there is enough time today to discuss all of the possible ramifications in fertility. One of my sort of pet peeves is that there is so much emphasis on the visible high tech reproductive technology that we lose sight of the fact that perhaps 85 percent of all couples will never be candidates for in vitro fertilization or any of these high tech things.

I think there is an awful lot of basic education of physicians, general practitioners, and even obstetrician gynecologists about how to conduct an infertility evaluation that needs to be done. I think the American Fertility Society, if you look at its membership doubling in the last 10 years has been one of the most important vehicles for this education.

I have the privilege of being in a tertiary referral center and every day I see examples of mismanaged basic infertility valuations. I see women who have gone through surgery only to find out that 2 years later the husband never had a sperm count. That's why that statement's in there and I think we could probably do much more for the infertile patients, infertile customers, infertile clients out there. I think we could get the information out as to what is the basic infertility evaluation, who is competent to conduct a basic infertility evaluation and when is referral to a specialist appropriate.

Chairman WYDEN. Let me ask one more question about the issue of stimulation cycles. Because I think it's important and relates to the count in some basic data. Now, I think we've established that in terms of the key elements is where one begins the count. Success rates vary greatly if you start with the stimulation cycle or with the egg retrieval, isn't that correct?

Dr. QUIGLEY. Do you mean how the count of stimulations acclimated vary, yes.

Chairman WYDEN. Yes; now many have said that we don't yet have the recipe for IVF. I think it would be fair to say that that's true for a number of stages. Is that correct?

Dr. QUIGLEY. I think it's especially true for the stimulation. I think the recovery process is quite well worked out at this point.

Chairman WYDEN. Even the ability to stimulate egg production is questionable, isn't it?

Dr. QUIGLEY. I think from the very beginning we've found that whatever we do works well in about 85 percent of women. It almost seems like no matter what we do there are 15 percent of women that we cannot get an adequate response. We're basically trying to fool mother nature, and she's better than we are.

Chairman WYDEN. So you can assume that the stimulation process is going to produce the necessary number of eggs, can you?

Dr. QUIGLEY. That's what we're aiming for and you know, with almost all patients we eventually have come up with a recipe to get an acceptable degree of egg production. We're certainly far from perfect.

Chairman WYDEN. But by using egg recovery rather than egg stimulation cycles some have said that artificially inflates success rates. Is that correct?

Dr. QUIGLEY. Again, it depends upon what you're going to use as your denominator. If you go on a per patient basis, everything will look better, rather than on a per cycle basis.

Chairman WYDEN. Now adding continuing pregnancies to live births is fairly common in terms of assessing data, isn't that correct?

Dr. QUIGLEY. It is very common and it has to be in order to reflect what a clinic is actually doing. But unfortunately everyone knows what a baby is and not everybody knows what a pregnancy is. I think all the speakers this morning have made a plea for reporting statistics in view of live born babies taken home.

Chairman WYDEN. But if you add continuing pregnancies to live births, doesn't that inflate the success rates again? Because my understanding is that 26 percent of all continuing pregnancies are likely to end in spontaneous abortion.

Dr. QUIGLEY. It depends on what you're trying to do, Mr. Chairman. If we're trying to give the patient an accurate assessment of what her chances are of getting pregnant if she goes through IVF in March 1989, you're going to have to give a combination of live births plus some percentage of continuing pregnancies. If you want to tell her what her chances were back in 1987 we can do that very very accurately by counting babies. But we're trying to show that things are getting better also.

Chairman WYDEN. I would only say that, first the obviously getting pregnant is not the same thing as having a baby and, second we agree with you in terms of getting this information out and that is why we have put this all on the survey for American families to get. But it seems to me that it highlights the need for some common, understandable definitions of success. I think that as this field continues to grow and grow at the rate that we see, this is going to be a very important issue for consumers. I would just say that in terms of the issues we've discussed this morning, I would put it at the top of the list in terms of voluntary action by the two groups. One, some guidelines with respect to advertising and ethical practices are crucial and second, to come up with some common standardized terms for success is essential. Those are going to be two areas that consumers are going to look at and certainly we're going to be looking at in the future.

Dr. deCherney, if I might, just a couple of questions for you. What are the qualifications for becoming a member of the American Fertility Society?

Dr. DECHERNEY. The American Fertility Society is a voluntary society. It's certain, professional groups speak are eligible physicians, obstetricians, urologists, nurse coordinators, some psychological aspects, but it's purely a voluntary society.

Chairman WYDEN. In effect, belonging to the Fertility Society means that an individual in the field has an interest in the field, rather than any particular expertise in the field.

Dr. DECHERNEY. Absolutely.

Chairman WYDEN. So someone could join the Fertility Society and, in effect, try to hold out that membership and that participation reflecting some kind of special expertise.

Dr. DECHERNEY. People do that commonly, but the Fertility Society does it's best to discourage that kind of behavior.

Chairman WYDEN. How do you do that? One of the things that concerns me, and we talked about this, is I have not heard of any actions specifically taken against those who are misrepresenting. Now, Dr. Younger talked about sending some letters and things of that nature, and I think that's certainly the first step. But to really send the message it seems to me that, at some point, there has to be action against those who misrepresent?

Dr. DECHERNEY. I think that that gets back to one of your subjects for the future. We do have an ethics committee, and I serve on that ethics committee, and I promise you that we'll bring that up. I think that's a good point and I think this is a place where the Fertility Society should enforce some rules about the use of their name as a form of advertising. I think that is unethical.

Dr. YOUNGER. I will tell you that when this has come to the attention of the Fertility Society that the executive director has written those individuals and in essence, has told them that it's inappropriate. That they should remove, particularly when they use the logo of AFS, or advertise in this degree, that that is improper and to remove it from their letterhead. They have not, however, been removed from the society for that.

Chairman WYDEN. I would very much like to see action in this regard, because it seems to me to really be another example of holding one's self out to be something other than what your talents and skills reflect. We will want to follow up with you in that.

Only one other question for you, Dr. deCherney. I gather that there's a fair amount of these weekend courses that are now being offered. Who is instigating them and is this yet another attempt to try to show some expertise and some training and hold out special skills that really aren't there?

Dr. DECHERNEY. There are two—well actually there are three, if it is for people to have courses. One is the noble one of the education. The second is somewhat in the way of financial reward, but probably the most compelling is that many States in this country insist that doctors get continuing medical education credits. This is how they get continuing medical education credits. I didn't mean to imply that these courses were a bad thing. In fact, I think these courses are good and I think that it's laudable. Medicine is one of the few professions that people into their careers continue to be educated.

What I meant to say, or what I did say is that people shouldn't use a 2-day course as a sign of expertise.

Chairman WYDEN. I just noted that you wrote an article on these courses. What really struck me is, and I quote, "most of these courses are of short duration, lack significant clinical training." You seem to conclude that based on course brochures the most important benefit from the course is "the certificate suitable for framing."

Dr. DECHERNEY. Yes; but that's from the person participant in the course, not in the person that's giving the course. So I was critical of that aspect. I don't want to come down hard on education. It's a big part of my business.

Chairman WYDEN. We don't either and educational programs, be they 4-hour programs, or weekend programs are obviously to be encouraged. But again, based on what I've seen and frankly just from reading your own scholarly articles, I would hope that the association would look more carefully at these courses.

Dr. YOUNGER. The American Fertility Society sponsored courses do not provide a certificate suitable for framing. We haven't for a long time.

Dr. DECHERNEY. The topics are usually so general as really not to provide a credential.

Chairman WYDEN. One other question that we had, concerns taking action against those who may be involved in some misrepresentations and questionable use of credentials and the like. Is there a concern in your groups that you may run afoul of the trade laws and be involved in the restraint of trade? Is that one problem that you've run across?

Dr. YOUNGER. I think as far as just the American Fertility Society views itself as an educational organization and probably has never seriously considered—since it's an open society, of doing things like this. However, our three affiliated societies do have certain requirements for membership. Maybe Dr. deCherney and Dr. Quigley, since they are very active in those societies, can point out some of the concerns of those.

Dr. DECHERNEY. But that surely is a rhetorical question, because even on a local level there were people in New Haven, CN, or Connecticut that were undergoing practice that didn't measure up to my scrutiny. I wanted to complain about that. That certainly would stimulate restraint of trade aspects of these practices, or practice.

Chairman WYDEN. I would just hope that this not be a significant obstacle. I was the offeror of the Health Care Quality Improvement Act that gives legal protection for physicians being involved in peer review. That certainly would be as applicable in this context as others. So I would hope that restraint of trade and the question of the legal status of peer review wouldn't be hampering some of these efforts.

Dr. Marrs, just a couple of questions for you, if I could. When you testified at our last hearing, you felt that, in your words, the industry was in danger of selfdestructing by those who in effect were taking advantage and skirting the rules, resulting in highly publicized cases of abuse and exploitation. What progress do you think has been made now since that hearing, what with the survey and the other efforts that have begun.

Dr. MARRS. I think there's a lot of progress that has been made. Number one, the biggest most important issue I think that's come before the public and before the physicians in our specialties is that the pregnancy rate is not 30, 40, or 50 percent. That in an honest reporting or in an open reporting, that the pregnancy rates range in the low levels, which we've all known but nobody's had the courage to talk about. I think that the importance of this publication of these data will allow a different mind set to take place. We don't have to convince our patients that we have a 20-, 30-, or 40-percent pregnancy rate because somebody down the road is doing that.

We now have the ability to say look at the results and these figures are what they are, and we're not dealing with unknown figures anymore. So I think the approach and the openness that this has generated is extremely important. That's something that has to continue.

The issue of whether the medical societies can control or peer review and direct activities of other physicians, I don't think it's ever going to be that way. I just don't think that we have, the American Fertility Society, or anybody else, we don't have the authority to do that. When we were forming SART, we went through several years of extreme debate about whether SART could even credential and ask for membership credentials requiring live birth outcome. We were criticized for even suggesting that to the membership. So I think it's very important that we look outside for support but have a combined support of various different professions to look for.

Chairman WYDEN. Do you think there should be an annual survey along the lines of what we have done this year?

Dr. MARRS. I think we have to come to grips with certainly the IVF registry report is one that's been established for several years. I think that's a very good mechanism in our scientific publications and it will continue and it's supported by the National Institutes of Health. I think it's extremely important that we continue that.

I think from a purely consumer or public situation, the consumer does not have access to the registry report. They would never know it existed. We put it in our office, we put it out for the patients to read. But they don't have access to it. So I think there has to be another form of reporting, whether it's from your committee or somebody like that that gives that information to the public.

But it may work, it may be easier for that to work in conjunction with the registry. You may not need two separate bodies doing the same thing. But a combined effort there would be possible.

Chairman WYDEN. I certainly think it's going to be hard for our subcommittee, certainly this chairman, to do this for the rest of his adult life on a yearly basis. I am very hopeful that the registry or some other program will develop and pick it up. The only other question I had is that you said recently that you had cause to review the last several years of scientific publications and found that it was very difficult to extrapolate live birth outcomes from a large percentage of the reports. Why did you feel that that was so difficult? It would seem to me that live births are live births.

Dr. MARRS. The scientific publications for the most part obscure that data. The data is there. You have to go in and extrapolate, you have to sit down and take the data and figure out what the live birth rate is based on the suggested percentages of miscarriages, stimulation cycles. What I'm looking for, and I think what's important to the patient as well as the physician in our related specialties is that we make that information clear to them. The physician reading those articles will sit down and say well, we've got a 30 percent pregnancy rate reported in an article this month. But what that really means is that there's biochemical pregnancies, preclinical abortions, spontaneous abortions, and a percentage of that will end up as live birth rate which is probably one third of what the article reports.

If he's not going to be sitting down and going through in detail and working out those percentages he's going to be talking to his next patients and saying well IVF offers you a 30 percent chance and we'll send you to this clinic or that clinic. They walk into the center and find out that the live birth rate is 12 percent.

So the physicians need the same accurate reporting as patients.

Chairman WYDEN. I think your comment is really one to quit on. We always used to say that when I played basketball. You wanted one last shot that would go in and you could quit on it. It seems to illustrate the whole concern of this subcommittee and that is that you're one of the most skilled practitioners in this field. If you come to the conclusion that I just asked about, that it's hard to extrapolate out scientific publication information about live births, think of how difficult it must be for American families to get that kind of information. So I think that really makes the case to continue our ongoing educational effort much better than anything I could conclude.

So I want to thank you for your help, thank all the panel members. We'll look forward to working with you in the future.

Our next panelist will be Gary B. Ellis of the Office of Technology Assessment. Dr. Ellis, we welcome you to the subcommittee. You are something of a guru of this whole field and its ever changing circumstances. I want to thank you for coming again and for the help you've given us for this hearing and previous hearings. I think you know our rules as well as any. Do you have any objection to being sworn today?

Dr. ELLIS. No, sir.

[Witness sworn.]

Chairman WYDEN. We will make your prepared remarks a part of the record in their entirety and if you could summarize some of your principal concerns that would be very helpful.

TESTIMONY OF GARY B. ELLIS, OFFICE OF TECHNOLOGY ASSESSMENT

Dr. ELLIS. Thank you, Mr. Chairman. Your choice of the word guru is momentarily unsettling. The last guru of note, the Bhagwan, was run out of your home State by the Immigration and Naturalization Service. [Laughter.]

Chairman WYDEN. I want to associate myself with your remarks.

Dr. ELLIS. I am Gary Ellis, Senior Analyst at the Office of Technology Assessment. Before I proceed, I too, want to salute the excellent work of the subcommittee staff. It's been a privilege to work with your staff, particularly D. Ann Murphy. Over the years we have had an opportunity to work with many committee staff and I can only say quite simply that other committee staff have much to learn from your D. Ann Murphy.

Last year OTA reported on the medical, scientific, legal, economic, and ethical issues surrounding infertility and medically assisted conception. Two reports were published. One called, "Infertility: Medical and Social Choices," and a second, "Artificial Insemination," which is a survey of the practice of artificial insemination in the United States. My testimony this afternoon focuses on developments OTA has observed in the wake of those reports.

At the outset, permit me to make a summary statement about in vitro fertilization and its allied procedure, GIFT. These medical procedures, which did not exist in the United States just 10 years ago, offer hope to infertile couples who may have lost hope, and moreover are delivering babies to couples who may have been unable to conceive without assistance.

About these simple and positive facts, there can be no dispute, and I emphasize them. The babies, the children are there. One clinic in Norfolk, VA, in January delivered its 500th baby conceived by in vitro fertilization. The looming question is at what cost, both financial cost and emotional cost, do these fulfilled hopes and babies come? Not only to the couples that are successful, but also to couples who are unsuccessful and to society as a whole.

Since OTA delivered its report, that question has been actively examined by this subcommittee, by the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government operations, examined in professional journals and in the print and the broadcast media.

The answer to the question, at what cost, is complex indeed. First, some perspective. This year there will be about 3.8 million babies born in the United States. As many as 5 percent of that total will be conceived with medical assistance. Americans spend about $1 billion a year on medical care to combat infertility. As many as half of the infertile couples seeking treatment are ultimately unsuccessful, despite trying various venues of treatment. That places infertility treatment well within the broad spectrum of success rates for various high tech and low tech medical procedures.

OTA estimates that in 1987 Americans spent about $70 million on some 14,000 to 21,000 attempts at in vitro fertilization. Some of that was paid by insurance companies and the balance by patients; insurance coverage for IVF is highly variable. Despite these statistics and its notoriety, IVF is a relatively rare procedure in infertility treatment. OTA estimates that less than 5 percent, and perhaps less than 1 percent of couples obtaining infertility treatment undertake either in vitro fertilization or GIFT, at present.

On average, 9 out of 10 attempts at IVF end in failure. Put another way, the percentage chance of delivering a baby after one IVF stimulation cycle is in the single digits. In 1986 on average, couples had a 6 percent chance of taking home a baby after one IVF stimulation cycle, according to data collected by Medical Research International and the American Fertility Society.

In January, the same authors published more recent data for 1987, but it is not possible to determine an IVF take home baby rate from their report. The subcommittee's survey of more than 140 IVF/GIFT clinics presented today indicates that the IVF take home baby rate for 1987 was about 9 percent per IVF stimulation cycle, as you said in your opening statement.

Other quotations of success rates are made from this very same data set. President of the SART group, Dr. Quigley, quoted 13 percent. I can only say that Dr. Quigley is viewing the data through glasses that show his preferred denominator. Thirteen percent is one calculation depending on what denominator is used. The more useful quote is to say nine percent babies per stimulation cycle.

It is important to note that human reproduction in its unassisted form is remarkably inefficient. Substantial embryonic loss is a routine part of the life cycle among humans and in fact among all mammals. Most eggs are never fertilized and if fertilization occurs, as many as one fourth to one third of human conceptions end in miscarriage, for reasons that are poorly understood.

The seemingly low success rates for in vitro fertilization must be thought of in the context of what happens in nature.

Much emphasis has been placed on success rates by both practitioners and patients. Some IVF clinics incorporate statistics about their success into their advertising, and I have brought along some examples this afternoon. OTA does not formally monitor the advertising of IVF clinics and has conducted no systematic evaluation. The examples I'm about to show were obtained on a chance basis, and from some instances from interested citizens who mailed them in to OTA.

The advertisements describe clinics as having the highest success rate in a geographic area. Advertisements list success rates in percentage form without giving the numerator and denominator of the rate. They list number of babies born at a group of clinics without disclosing how many were born at a specific clinic in the group and so forth.

So with your permission I'd like to examine these examples. By the way I am assisted this afternoon by my OTA colleague, Tim Condon. Dr. Condon is a major contributor to OTA's work on infertility. His role here at the moment belies his true importance.

This first ad appeared in the January 1989 issue of the Washingtonian magazine. This happened to be the only one that I found myself. The next five were sent in by citizens. For a GIFT program in the Washington area, the advertisement makes some very specific and testable statements. The ad states that this particular GIFT clinic is the largest and most successful GIFT program in the Washington area. Until this afternoon with the release of the subcommittee's data, there was just no way for a patient in the Washington area to evaluate that claim. But the subcommittee today has broken that code of anonymity that existed in reporting success rates.

The ad makes a broad statement: GIFT, the latest and most successful treatment for infertility. I had to smile when I heard Dr. Younger state that of the many advertisements that he's examined and others have examined, in each instance the ad actually was found to be not lying.

Now here's a statement that GIFT is the most successful treatment for infertility. In the course of OTA's work we repeatedly asked physicians what are the most successful treatments for infertility? The responses were: drug stimulation, drug therapy to induce ovulation, surgery to correct tubal defects, and artificial insemination. I don't recall a single physician responding by saying that GIFT was the most successful treatment for infertility. Perhaps this ad meant to say that GIFT is a very successful new reproductive technology, or a successful noncoital treatment for infertility. The ad might have said that, but it does not.

The next ad was collected by a travelling OTA employee, from the Chicago Tribune last July 1988. I'll have to read it to you because the type is perhaps too small to see. This ad is actually not a bad example. This ad has taken a step forward in advertising where it lists a percentage. It says this clinic reports a confirmed pregnancy rate of over 30 percent, so that's confirmed pregnancy in the enumerator. The denominator, however, is still lacking. A confirmed pregnancy rate of over 30 percent for couples undergoing in vitro fertilization is a clear numerator, but undergoing in vitro fertilization doesn't give us a denominator. We don't know if the denominator is stimulation cycle, egg retrieval, or embryo transfer.

Again, the next sentence: where more than 20 percent of IVF attempts result in the live birth of one or more children. You've got the numerator there, it's live births. We don't know what the denominator is. This ad takes a step in the right direction, but we still need more specifics whenever percentage is mentioned.

My mother-in-law in Plantation, FL, clipped this from the September 1988 issue of Better Homes and Gardens. The ad ran in the Southeast edition of that magazine, covering the Southeastern United States. An ad from the the Fertility Institute of Boca Raton. I've got to ask you to study the ad—its very attractive. A picture of babies, obviously attractive, and the Fertility Institute is producing some very satisfying results. If you line up 10 people and ask them, look at that, and then say what is a very satisfying result depicted by that ad. There's no ambiguity there whatsoever. It's taking home a baby. I'll read the first three sentences there slowly: "In fact, 4 of our first 12 patients participating in our IVF program have achieved pregnancy." There's a fact, 4 of the first 12 patients have achieved pregnancy. "Our first test tube baby is due this October." A the baby hasn't been born yet in this clinic. "Our success rate is an impressive 30 percent, well above the national average." Now, success clearly can't be live babies born. The advertisement indicates that states no babies were born yet: the first one is expected in October.

Presumably, and I'm only guessing, that 30 percent is a reference to the 4 of 12 patients who achieved pregnancy.

An avid reader of Better Homes and Gardens, Phyllis Lipof of Plantation, FL, sent this next ad from the December 1988 issue. Essentially the same ad from Boca Raton but one sentence is missing, it's the third sentence from the opening paragraph that said "our success rate is an impressive 30 percent, well above the national average." There are several possibilities why this sentence is gone. Perhaps somebody complained that it was ambiguous and the copy writer took it out. Perhaps, although 4 of the first 12 patients were pregnant, subsequent patients did not get pregnant and so it would now be in fact, wrong to put that 30 percent rate in.

I had a chance to review the data that was collected by the subcommittee and it was very easy for me now to go and look at this clinic and although I haven't yet had a chance to go through the data in the detail I would like, it appears to me that 4 of the first 20 patients at this clinic were pregnant. That would mean 4 of the first 12, yes, and then zero for 8 from that point. The question one might ask then of this clinic, knowing the next string of patients, knowing it was zero for 8, is it proper to retain this sentence, that 4 of the first 12 were pregnant? Is that full disclosure? The ad speaks for itself, and you can answer that question for yourself.

This next ad ran in the New York Times. A freelance writer, Andrea Eagan sent it in. I think Andrea's in the room today. We thank you. In vitro fertilization, it says the facts, from IVF Australia, United Hospital in Port Chester, NY. From your survey data, Mr. Chairman, it's very clear that this is a successful program. The statistics are most impressive. They state in the advertisement that 236 babies were born to date in IVF Australia programs, plural, programs. There are at least two programs in the United States operating under the name IVF Australia. Another one is in Boston, MA.

This next ad ran in the Boston Globe. Both of these ads ran in September 1988. You can see they're promotions for patient education events that are going to occur that month. This ad for IVF Australia programs running in the Boston Globe with a Boston address contains the very same sentence that the ad from New York contained: IVF Australia programs, plural, have led to 236 babies being born. Again, as Dr. Younger said, the ad can probably be found to be not lying, technically it's true if it says IVF Australia programs are responsible. As far as I can tell this ad ran when the Boston program was about 3 months old and it doesn't appear from reviewing the statistics that the Boston operation has yet—even in March—had a baby born. So the question politely put is this the most forthright presentation of information to an infertile couple in the Boston area reading the Boston Globe looking for care at this address in Boston? Where were the 236 babies born, which team did it, and in what city?

These are some examples that we collected. Advertisements such as these are less than forthright in the ways in which they present information. That's both troubling and inappropriate in a field in which forthrightness is absolutely necessary. The fact is that the odds do not favor successful pregnancy for couples undertaking IVF and complete and realistic disclosure is a must.

In that vein, it is remarkable to find in a patient education booklet distributed for placement in physicians' offices the following. "Test tube baby or in vitro fertilization programs have a 10 to 25 percent success rate per attempt." No; they have a 0 to 25 percent success rate per attempt. This patient information booklet was published in 1988 by the American Fertility Society.

In the area of consumer protection, Congress could direct the Federal Trade Commission to exercise its authority under section 5(a)(6) of the Federal Trade Commission Act to determine whether advertisement of success rates at various IVF or GIFT clinics is misleading, and if so to issue appropriate regulations. Regulations could be issued, for example, to standardize the ways in which success rates are reported so that individuals are better able to make an informed choice about whether and where to undergo a procedure.

The most useful annual reporting by IVF/GIFT clinics would include at a minimum, six numbers. That's the number of patients stimulated, the number of stimulation cycles, the number of embryo transfer cycles, the number of clinical pregnancies, the number of pregnancies delivered, and the number of multiple pregnancies delivered.

As I said previously, until the release of subcommittee's survey today, success rates of individual clinics were not publicly reported in a standardized manner. This has made it extremely difficult for infertile couples to be fully informed consumers. In fact, it has created in this area of medicine a situation where the doctor-patient relationship is fast becoming a vendor-consumer relationship. This ethic in a vendor-consumer relationship can be one of caveat emptor, let the buyer beware. This sets up physicians and patients as adversaries and is not appropriate. Physicians are more properly advocates for their patients.

The efforts of the subcommittee in publishing clinic specific data are an important step, Mr. Chairman, for reversing an inappropriate trend in this area of infertility treatment.

Beyond the issue of reporting by individual IVF clinics lies the fundamental question of substantially improving success rates. In this regard the ultimate consumer protection is research. Government sponsorship is desperately needed for research protocols that could advance basic scientific understanding of human reproduction and improve the prospects of success for infertile couples.

In July 1988, the Department of Health and Human Services announced plans to revive its Ethics Advisory Board, a body that ceased to exist in 1980. The Ethics Advisory Board is required to advise the Department of Health and Human Services on the ethical acceptability of the conduct and funding of certain proposals for research involving human subjects. A proposed charter for the board was published in the Federal Register on September 12, 1988, and about 175 comments were received from the public. To date the Department of Health and Human Services has not delivered on its pledge to publish a final charter and revive the Ethics Advisory Board.

In the absence of the Ethics Advisory Board, research funding has been blocked in this area. With ethical issues playing increasingly prominent roles in biomedical and behavioral research, it is appropriate that certain research proposals be reviewed not only for scientific merit, but for ethical acceptability as well. Few will dispute that respect for societal values is requisite to accepting public funds for research. The proposed Ethics Advisory Board is scheduled to be the chief interpreter within the Department of Health and Human Services of the ethical acceptability of biomedical and behavioral research as the Nation enters the 1990's. Research with human subjects falling under the Board's purview may include that with healthy human subjects as well as demented patients, children, prisoners, AIDS patients, fetuses, and human sperm and eggs.

In the case of human sperm and eggs, the prolonged absence of an Ethics Advisory Board has essentially halted research in human in vitro fertilization. Such a Board is required by Federal regulation to advise the Department of Health and Human Services. With no board, no grants can be funded. Investigators do not submit proposals involving human IVF because of a widespread awareness of this de facto ban on such research. The dimensions of this chilling effect of the moratorium on IVF research are such that the NIH estimated to OTA that it might receive more than 100 grant applications related to human IVF if the Ethics Advisory Board existed today.

Some funds for IVF research come from pharmaceutical companies, institutional, and departmental funds, and patient fees. But any Federal component is missing. The 9-year absence of an Ethics

Advisory Board has thus robbed infertile couples seeking IVF of the ultimate consumer protection—as I said before—research.

Mr. Chairman, that concludes my testimony, and I thank you for the opportunity to present OTA's analysis of trends in medically assisted conception. I will be pleased to answer any questions.

[Dr. Ellis' statement may be found in the appendix.]

Chairman WYDEN. Dr. Ellis, thank you. Thank you for an exceptional job over a very long period of time in working with us on this and other issues. Now you said in your statement that you couldn't determine the IVF take home baby rate from data that was collected by the American Fertility Society. Why is that?

Dr. ELLIS. First, I was speaking about the so called registry of IVF data published in January 1988 in Fertility and Sterility. The data presentation lumped together IVF stimulation cycles and GIFT stimulation cycles. So it was just not possible to determine from this report how many women underwent IVF stimulation in 1987. Without that figure, that denominator, I cannot calculate a take home baby rate for stimulation cycles for IVF.

Chairman WYDEN. I want to make sure that I understand the significance of this. Because this seems to me to be very important point. The IVF Registry that you're talking about is the official IVF Registry of the professional society. What you're saying is that it doesn't have this basic statistic of how many IVF babies there are per IVF stimulation cycle. Is that correct?

Dr. ELLIS. That's correct, Mr. Chairman. I must say that perhaps it's because the American Fertility Society, and I can only guess, has not really focused on or accepted stimulation cycles as the denominator. The brochure that was brought by Dr. Younger forward this morning, for example, lays out for the patient three ways, I'm quoting now, "three ways to determine the take home baby rate." These three ways are various calculations that use egg recovery for the denominator, or embryo transfer for the denominator. But the description by the American Fertility Society of ways to calculate the take home baby rate does not include a method that uses stimulation cycles.

Obviously, I attempted to make this calculation in preparing my testimony, to compare the registry take home baby rate with your report this morning, 9 percent. I wrote to the author, Medical Research International, seeking that information and, without going through all the details, I received a form letter in response telling me that they've received many requests for additional information, that a committee was being formed to handle those requests.

Subsequently, I received a call from Dr. Quigley who explained to me that the information collected by the registry just did not contain the precise number of IVF stimulation cycles distinct from GIFT stimulation cycles. So I have no reason to believe that the publication of the registry, for example, withheld an important piece of information. It just was not collected, as far as I can tell.

Chairman WYDEN. In your view why is it so important to collect success rates based on the initial stimulation cycle? We've of course, heard this morning about calculating it based on eggs retrieved or embryos transferred, other approaches. Why do you think it's so important to proceed with the initial stimulation cycle as the primary way of going after it?

Dr. **Ellis**. I could answer in several ways and perhaps I will. First of all, it is very clear from the data that the subcommittee collected that about one in four women don't proceed to ovulate following stimulation. That is a fact derived from the data collected by the subcommittee. I'll say it a different way. Stimulation is successful about 75 percent of the time. Three of four women proceed to ovulate in response to stimulation.

Dr. Quigley talked about the small fraction, just moments ago, of women who don't proceed to ovulate. He used the number 85 percent to illustrate the number who do proceed to ovulate. All I can say is that the data presented this morning indicate that figure is about 75 percent, I believe, and the registry shows that data too. I believe that the combined IVF and GIFT stimulation data in the registry, about 73 percent of the women proceeded to ovulate following stimulation. I'll just summarize by saying one fourth don't proceedto ovulate following stimulation.

The question is: Have these women attempted in vitro fertilization? Have they attempted IVF, these women being stimulated? In a very real way, yes. They have. What you're really asking is when does the process begin for a patient. What I'm maintaining is the attempt at IVF begins with that initial hormone treatment, and success rates must be projected from that point. Dr. Quigley said in his testimony that the proper denominator is egg retrieval, for three reasons, he stated, because the risk begins at that point, the cost begins at that point, and the pain begins at that point. Trusting my memory, more or less that's what he said.

We've heard from others this morning and we can sense that the cost does not begin with egg retrieval. Dr. Marrs uses a figure of $2,000 for the costs prior to egg retrieval. I had a good sense that stimulation was not being offered at no cost, and perhaps as Dr. Marr testified, the cost is very great. The risk, I think we'd have to ask Dr. Quigley if he really wants to maintain that the risk to the patient begins with egg retrieval, this is a minor surgical procedure; or if the risk to a patient begins when drugs or hormones are introduced into her body.

Finally, the pain? There are several kinds of pain. Let's talk about psychological and emotional pain. Let me address that by asking where does the investment begin for the patient, both financial and emotional? I would maintain that the investment certainly begins when the first stimulation cycle is undertaken. I feel that I speak conservatively in saying that. The investment for the patient begins when she and her partner begin to contemplate taking the IVF route. The investment for the couple begins when they look to the telephone to pick it up to make that appointment at the doctor's office, when they begin to think of what time they have to take off from their job to begin to undergo examination and stimulation cycles.

It is just very hard for me to accept any other calculation. The image that I use of the couple facing in vitro fertilization is that the're standing at a stair case, and there are several steps. They ascend each step but not all couples starting on the staircase will proceed to ascend it fully. There's a loss at each step, procedures are unsuccessful at each step. The two different ways that I'm illustrating of calculating the height of the staircase are do you calculate the height of the staircase, let's say there are seven or eight steps, do you calculate the height of the staircase from the first step to the last step. Or do you calculate it from the middle of the staircase to the last step? I hope that's a good image. But my answer is you calculate the height of the staircase from the first step to the last. You don't start arbitrarily in the middle because that's the way you feel it should be done, or that's the way that it is easiest to calculate or that you're most certain of.

I can't help but note the irony that we've heard Dr. Quigley state and others stated also that the most important criterion or one important criterion for admittance to the SART group, the Society for Assisted Reproductive Technology, is the number of stimulation cycles. Yet, these witnesses maintain that the most important number for the patients is not stimulation cycles but egg retrieval cycles. I find that ironic and I think it begs for explanation.

Chairman WYDEN. You also said that the Government's performance with respect to research is still very very poor, and I recall you telling the subcommittee the same thing last June. What you're really saying is that we had 9 months to deliver and still nothing's happened.

Dr. ELLIS. Not merely 9 months to deliver, but 9 years. The world's premier biomedical research institution, the National Institutes of Health, coming up now on almost 11 years after the first test tube baby was born, the NIH still stands at the starting gate in this field of research. The absence of an Ethics Advisory Board has stifled research.

This subcommittee, Mr. Chairman, deserves very high praise for confronting where no one else did, including the profession itself, for confronting the question of useful clinic specific reporting of success rates.

But even that meritorious effort cannot improve those rates. Research is desperately needed. I know that oversight of research within the Department of Health and Human Services, that does not fall within the purview, the jurisdiction, of the subcommittee. I could suggest, Mr. Chairman, I'm certain you're already aware that your senior status on another subcommittee, the Subcommittee on Oversight and Investigations of the House Energy and Commerce Committee provides a most effective venue for examining the other side of the consumer protection coin, namely research.

Chairman WYDEN. Again let me thank you. We couldn't be here, we couldn't be getting this information out without the tremendous help you've given. Suffice it to say we've got an enormous agenda on our plate now as a result just of what we've heard today and in areas where we have to follow up.

I didn't ask you any questions with respect to the Federal Trade Commission because your views on that have been so clear, but we're going to hear from them. I just want to note for the record that I am very much in support of what you are talking about with respect to the Federal Trade Commission as well.

I think they have just been absolutely asleep with respect to this issue. It is time to come out of the regulatory slumber and take some steps to protect the families from some of the misrepresentative advertising that you, in particular, have talked about. I think you can debate whether advertising is completely misleading or fraudulent or something of that nature. But it is quite clear to me that consumers are not getting the entire picture. That is what is relevant here in an area where they are so vulnerable, where they are spending lots of money. You have made the case very well.

Dr. **Ellis**. If I might make one closing remark, Mr. Chairman. You just reminded me, earlier this morning Dr. Younger in his remarks pledged that it was the American Fertility Society's interest and goal to provide accurate information. In your questioning of Ms. Williams, you indicated that you'd like to know, was she provided with useful information. That crystallized what we're talking about, when we talk about the advertisements. There is a need for useful information. There is a pledge to deliver accurate information. Those are two different things. Thank you very much.

Chairman **Wyden**. Thank you, and we look forward to working with you in the days ahead. Our next panel, Dr. Stuart Hartz, Ph.D., president, Medical Research International of Boston.

Doctor, we welcome you, I see you're on your feet having already seen the way this committee deals with its procedures. You have no objection to being sworn?

Dr. **Hartz**. No.

Chairman **Wyden**. Please rise and raise your right hand.

[Witness sworn.]

Chairman **Wyden**. Doctor, we will make your prepared remarks a part of our record in their entirety. If I could ask you just in the interest of time to try to summarize in 5 minutes or so, your principal views, that will allow us some time for questions.

TESTIMONY OF DR. STUART C. HARTZ, PRESIDENT, MEDICAL RESEARCH INTERNATIONAL

Dr. **Hartz**. Anybody knowing me would know that's difficult. However, thank you, Mr. Chairman. My name is Stuart Hartz and I am president of Medical Research International, a health research consulting organization located in Burlington, MA.

We specialize in the design and conduct of clinical trials and epidemiologic studies on the effects of health care products and procedures. I also hold faculty appointments in Community Health at Tufts Medical School, and the School of Public Health at Boston University in Epidemiology and Biostatistics.

On behalf of our organization, MRI, and the 155 U.S. member clinics, I appreciate the opportunity to offer my perspectives on the IVF registry. The registry, as you've heard this morning, is a collaborative effort of the American Fertility Society, SART, and our company. All registry operations are performed by MRI at its central offices. Since its inception, the registry has been financially supported exclusively by Sorono Laboratories. In June 1988, MRI was awarded a contract by the National Institute of Child Health and Human Development, NICHD, to study the potential adverse health effects on women undergoing assisted reproductive technology treatment.

The registry was established to explore the epidemiology of the assisted reproductive technologies. Its major objectives include describing the patterns and nature of these procedures, measuring the relative efficacy of various procedures with respect to clinical pregnancy initiation and outcome, determining the impact of new or modified research advances in this area, and detecting potential adverse effects associated with the assisted reproductive technologies.

A critical role of the registry as you've heard this morning is to disseminate the results of its statistical analyses through publications and presentations in the medical literature and at professional meetings. In addition, the registry acts as the central information source for the media seeking national statistics, By placing its findings in the public domain through both medical and lay media, we hope to make those findings available indirectly to patients.

We also seek to utilize community resources, such as Resolve, which is currently collaborating with us on our NICHD project by offering cooperating subjects gift memberships as an incentive for volunteering in the study subject. Planning and organization began in 1985 when physicians, within the framework of the AFS, were organizing SART, which at that time was referred to as the IVF Special Interest group. One goal of this new society was to develop an ongoing registry that would enroll its member clinics.

Presently, we at MRI and the Registry, seek to enroll all U.S. clinics using the assisted reproductive technologies, and to publish an annual report in Fertility and Sterility.

The goals and methods of the registry were first presented to practitioners along with the initial plans to organize SART, at the 1985 annual meeting of AFS in Chicago. At this meeting we emphasized that the data submitted by each clinic would remain confidential and would be published as pooled or summary statistics.

No one outside of MRI's registry staff has access to clinic specific information. The computerized data base does not contain patient names; and clinic identifiers are encoded using a special dictionary. During 1986, MRI developed and field tested two of the current methods for collecting and processing the data collected.

Clinics forward their data using either a PC software system that we developed for them, or a set of paper forms summarizing each clinic's treatment and outcome results. The data forms provide the registry with a clinic's overall or summary results pooling over all patients, while the software system allows clinics to record patient specific and cycle specific information.

The registry reports its findings on a calendar year basis and asks clinics to begin submitting each previous year's data in the beginning of next year. Follow up to determine outcome of ongoing clinical pregnancies continues until October at which time an article is prepared and submitted to Fertility and Sterility in the next available issue.

The registry officially began its operations in January 1987 and by the fall of 1987 a total of 88 of the then 169 estimated U.S. clinics had enrolled. The registry's first annual statistical report appeared in February 1988, and it summarized the 1985 and 1986—retrospective—data submitted to it by 41 clinics.

Yes; 1987 was very much a learning year for us, for SART, MRI, and the clinics themselves. Many clinics had never participated in a data collection effort using standardized procedures and definitions, or had to meet prescribed deadlines for data submission.

But by the end of 1988 data collection, last fall, we could report a total enrollment of 109 U.S. clinics in 38 States, 96 of which were prepared to submit 1987 calendar year data for analysis and publication. These results were recently published in the January Fertility and Sterility article.

I'll just briefly cite some of the statistics and look forward to responding to Dr. Ellis's comments regarding stimulation cycles. During 1987, the 96 clinics enrolled 10,397 patients and initiated 14,647 IVF stimulation cycles, of which 74 percent resulted in oocyte retrievals. For IVF alone, 87 percent of these retrieval cycles resulted in an embryo transfer cycle.

Ninety percent of the clinics had at least 1 delivery, and overall a total of 1,858 babies were born, 1,260 through IVF and embryo transfer. The overall delivery rates based on retrievals were 11 percent for IVF, 18 percent for GIFT, 20 percent for GIFT in combination with IVF based only on 199 retrievals. In each of our publications, we presented limited case reports on all reported congenital malformations and chromosomal abnormalities. However, due to the relatively small number of cases observed to date, we have not yet prepared a separate publication investigating their occurrence. We constantly monitor the data base for potentially important adverse effects warranting publication in the medical literature.

A major concern of the registry is the quality of the information submitted to it. Concerns have been raised regarding several potential forms of bias that could affect the validity of the registry's results. After all, the registry has limited resources and cannot send trained auditors around the country to each and every registry clinic. If indeed that is feasible or desirable, which I don't think it is.

So what makes us believe that the registry's efforts result in useful and valuable statistics? The registry's voluntary and confidential data collection methodology not only helps to optimize clinic enrollment and cooperation, but it also helps to minimize biased reporting. Since individual clinics are not identified in any of the registry's publications, they are neither rewarded nor penalized by their reported levels of success or failure.

There appear to be no incentives for individual clinics to submit false data or to selectively report only certain types of patients and/or outcomes. This traditional approach to guaranteeing the integrity of research information remains a fundamental registry strategy.

Alternatively, one would have to argue that there is collusion among the subset of clinics to submit false data. This appears unrealistic for several reasons, chiefly the incredibly complex and time consuming tasks required, both from statistical and computing perspectives. The registry's design and methodology played a major role in MRI receiving the NICHD award to conduct the follow up study of women undergoing assisted reproductive technologies. As is normal in such situations, the scope and quality of the registry's data collection methods were peer reviewed by an independent NIH panel prior to the award. We believe that this approval lends credibility to the registry's overall research design.

We continue to receive several inquiries a week regarding membership and each week we approach our goal of monitoring all U.S.

clinics was estimated to number approximately 200. Of the current 155 U.S. members, some 85 are members of SART, or 55 percent, and it is expected that this percentage will only increase with time. These 85 clinics, however, account for approximately 80 to 85 percent of the registry's patient stimulation cycles.

As the registry continues to expand I can envision several important new initiatives that it might take. One, for example, would be a separate research effort to enroll and monitor the growth and development patterns of the offspring resulting from the existing reproductive technologies. Currently the registry restricts its limited observations on the offspring to those recorded congenital malformations and chromosomal abnormalities detected at birth.

Currently, we do not have the financial resources to perform a follow-up study analogous to the one being conducted on the patients. Another new responsibility would have the registry act as the coordinating site for large multicenter intervention clinical trials aimed at testing the relative efficacy of innovative assisted reproductive technologies. However, as with similar research programs its future value relies on the critical support of the physicians and staffs at the clinics delivering the assisted reproductive medical care, the AFS and SART, on our current funding sources—Serono for the registry, and the NICHD—for the follow-up study, and the patients and their community based advocacy based organizations, such as Resolve.

In closing I would like to convey the enthusiasm and commitment that we at MRI have in carrying out the registry's mission and in seeking ways to ensure that it plays a meaningful role in measuring the future contributions of the assisted reproductive technologies. Again, thank you for the opportunity to appear before you and I would be pleased to answer any questions.

[Dr. Hartz's statement may be found in the appendix.]

Chairman WYDEN. Thank you very much, doctor. Let me start by following up on this point that Gary Ellis made. Dr. Ellis said that the official IVF Registry doesn't contain this basic statistic of how many IVF babies there are per IVF stimulation cycle. What is the problem here, or is there one in your view? He says that he contacted MRI and I gather never was able to get an answer.

Dr. HARTZ. The lack of complete information, reflects an artifact in our data collection method which has been corrected. In fact we're already receiving 1988 data that does allow us to stratify and identify stimulation cycles separately for IVF and GIFT. Perhaps I can provide you with some insight into this process.

First, the bulk of our data still is returned to us in paper forms. These paper forms last year did not allow us to distinguish between the initiation stimulation cycles between IVF and GIFT separately. We could, however, combine both IVF and GIFT together to estimate that a total of nearly 15,000 stimulation cycles were performed in the U.S.

It is known and well accepted as even Gary implied, that there is a reduction between stimulations and retrievals of roughly 25 percent. We provided the data in our article to allow for the adjustment in the overall live birth rates of 12 to 13 percent, which could be adjusted downward to 10 percent if you assume that only 75 percent of the stimulation go on to retrieval.

This was, by the way, I should mention our error in the paper forms, not SART's, and also it was based on the assumption that more of the clinics would be returning patient specific information to the computer.

Chairman **Wyden**. But with respect to the basic point, you do not dispute what Dr. Ellis has asserted?

Dr. **Hartz**. No.

Chairman **Wyden**. You believe it's being corrected and that this will be changed?

Dr. **Hartz**. Yes; the corrected 1988 data form has been submitted to all of the registry members and we have about 40 percent of the returns in already.

Chairman **Wyden**. Reading your testimony and going through your materials, I get the impression that you feel perspective patients are well informed about the existence of the registry and that patients refer to it for educational purposes?

Dr. **Hartz**. That's more a hope.

Chairman **Wyden**. It seems to be a statement and, hope, I don't quarrel with. But I just really question whether patients are well informed about the registry. At this point we have had a number of witnesses already and none of them had any idea of where to turn, Doctor. I have spoken with many patients myself personally, and they are absolutely in the dark with respect to where to turn. I think that it would be a delusion to consider otherwise.

Dr. **Hartz**. Absolutely; let me respond on two ways. Number one, the registry was never set up to be a patient information resource. It was never created to provide clinic specific information, as I mentioned, as either written or oral reports. The view is that this registry is a research resource and through the traditional methods of publishing in the medical literature, we hope that these data will become available to patients.

I should also add that our organization is only one town away from Resolve, and Resolve invited us to write an article in the Resolve newsletter that goes out to tens of thousands of women. The registry did write a column in their newsletter and that's the——

Chairman **Wyden**. But it would be fair to conclude that at present the registry is essentially a tool for the clinics rather than for the couples?

Dr. **Hartz**. It is a research tool for the public health and clinical communities.

Chairman **Wyden**. Now, the registry, I gather is also concerned about the nature of the reporting and the fact that it's anonymous and how that data of gathered. Do you think that there should be some independent verification done if the data that's collected?

Dr. **Hartz**. Independent, we view ourselves somewhat independently. If we could, with additional resources——

Chairman **Wyden**. No one's disqualifying anyone, I'm talking about someone going out and verifying——

Dr. **Hartz**. We would propose that the methodology that we're using in our NIH study be followed in the registry. That we be able to recruit with the sufficient resources, nurse monitors or trained professionals, who could go to the clinics and verify the information being returned to us in the registry. However, that is a very costly procedure, but certainly a desirable one in any epidemiologic practice.

Chairman WYDEN. One of the concerns that's been reflected to the subcommittee is that there's a limitation in the way the data is gathered because live birth rates for each don't really distinguish between the calendar year of embryo transfer and the calendar year of delivery. Do you agree with that, is that a limitation that would make the data misleading?

Dr. HARTZ. We have purposely related the births to the year of transfer. In the prior calendar year in which stimulations were initiated, we follow ongoing pregnancies for 9 or 10 months into the next calendar year. Thus, in our most recent publication we had less than 1 percent of unknown outcome for clinical pregnancies.

Chairman WYDEN. Now, clinics who report the data to the registry represent only about half of the clinics who are now practicing reproductive technologies. Do you think this gives us enough data to draw conclusions about the pattern, nature, and successes of reproductive technology?

Dr. HARTZ. The 96 clinics in the most recent publication, represents approximately 75 to 80 percent of the stimulations being performed in this country. Second, we now have 155 clinics in the registry and presumably our next report will be more generalizable to the entire U.S. clinic population, and will include both small clinics and large clinics. The growth in the number of clinics enrolling in the registry has increased dramatically over the last 2 to 3 years and in a sense we're playing catch up.

At the close of this year, we will have a baseline of 155 clinics and we seem to be closing in on our goal to monitor all U.S. clinics.

Chairman WYDEN. I gather that you feel that what the subcommittee has gathered is essentially consistent with what the registry has been able to gather as well.

Dr. HARTZ. Since I've been away from my office, I haven't had a chance to really review the data. But based on the preliminary summary statistics it certainly appears to be comparable and I appreciate your validating our report.

Chairman WYDEN. We very much want to work with the registry in the days ahead. I consider the registry an exceptionally useful tool. The effort to promote these technologies with such promise for American families has got to be a partnership between providers and families and Government. I look to build on the registry. It seems to me the registry is already a useful tool for clinics and practitioners. The question, is can we make additional changes so perhaps you all can do the kind of thing that my subcommittee has done this year in gathering information that really could be made available to couples who are trying to get the basic information they need so they can make a choice that's as important as any family confronts.

Dr. HARTZ. Thank you, I appreciate that. I think also the NIH now through its award, the first in IVF population research, is beginning to recognize that. I hope that we're held to the same scrutiny of quality and scientific rigor as everyone else in the public health research community.

Chairman WYDEN. You are going to be asked to play a bigger role in the days ahead and we'll look forward to working with you.

Dr. HARTZ. Thank you, same here.

Chairman WYDEN. Our last witness is from the Federal Trade Commission. Mr. William MacLeod. Mr. MacLeod, we welcome you. You have been very patient, and I appreciate it and I think you have heard the Chair make some relatively strong comments about the Federal Trade Commission over the course of the morning, and we welcome you here. You are on your feet because you understand the rules and you have no objection to being sworn?

Mr. MACLEOD. No; I do not.

Chairman WYDEN. All right. Raise your right hand.

[Witness sworn.]

Chairman WYDEN. Thank you very much. You have appeared before us before and we appreciate your cooperation in this case as in the previous instances as well. We'll make a copy of your prepared remarks a part of our hearing record in their entirety and if, perhaps, you could summarize some of your key views that would be very helpful.

TESTIMONY OF WILLIAM MACLEOD, DIRECTOR OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION

Mr. MACLEOD. Thank you, Mr. Chairman. My name is William MacLeod and I am the Director of the Bureau of Consumer Protection at the Federal Trade Commission. I am happy to have the opportunity today to appear before you and discuss the Commission's involvement in the policing of fraud perpetrated against a most vulnerable group, infertile couples. By infertile couples I mean those who have been trying without success to have children.

I should note that my testimony today is that of the Bureau of the Consumer Protection and the Chairman of the Federal Trade Commission, but not necessarily that of the Commission or any individual commissioner.

As the committee has heard this morning, this is an industry that is a substantial and growing industry. The OTA estimated that infertile couples spent as much as $1 billion in 1987 to combat infertility and as the chairman has made clear in his surveys and his releases, the IVF portion of that at $30 or $40 million and growing, is also that of an industry of some significance.

In my remarks today describing the Federal Trade Commission's activity I do want to emphasize one point and that is because the treatment of infertility generally is practiced by physicians at a local level, consumer protection efforts ordinarily rest with State medical boards and offices of State attorneys general. Our intervention in this area should be cautious and selective. Nevertheless, as our enforcement experience demonstrates, the Commission can play an important and useful consumer protection role under the general authority provided by section 5 of the Federal Trade Commission Act.

As you know, Mr. Chairman, section 5 declares acts or practices that are deceptive or unfair to be unlawful. Deception in the sale of infertility services, like other forms of misrepresentation, falls within the parameters set forth in the Commission's deception statement. Briefly, that deception statement says that if there is a representation, omission, or practice that is likely to mislead consumers acting reasonably under the circumstances and the representation or omission is material, then we have deception. Moreover we have held that it is an unfair deceptive practice to make an objective product or service claim without a reasonable basis for believing that claim is true at the time it is made.

We have a policy statement regarding substantiation and the level and type that is required depends on a number of factors relating to the type of claim. Let me describe briefly how these principles can apply to specific activities in the field of infertility services. One type of abuse that is especially likely to attract our attention is the misrepresentation of success rates. As the OTA report stated, not only do those success rates vary considerably, but they are also reported in various ways. For example, some clinics may claim particular success rates on national statistics even though the clinic itself has been operating for years far below the national averages. Consumers may well be led by such claims into a mistaken belief that their likelihood of achieving a pregnancy is higher than it is.

In other instances, success may be reported in terms of achieving a clinical pregnancy, which rate might be more optimistic than that of actually taking a baby home. To the extent that infertile couples are misled by claims such as these, they can suffer severe emotional and economic harm.

Other practices of interest to us would be false claims of guaranteed success, the use of drugs to trigger false positive pregnancy tests, the falsification of test reports indicating that a woman has achieved pregnancy and similar conduct. Our attempt to halt practices such as these should not be construed, I should add and emphasize, as any interest in policing of malpractice or neglect in the provision of medical services. Our interest is limited to deception and the marketing of fertility services to unwary consumers.

I mentioned briefly the aggregate cost of infertility treatments, it's also important to note those costs on an individual basis. We have heard numbers today of $6,000 and more, and this is a significant financial expenditure and one which should not be made on the basis of deception or misrepresentation. We should also recall the nonmonetary costs of fraud in this area. A failure to achieve conception, particularly if that was guaranteed by the provider, can exact a terrible emotional toll.

As you know, in January, the Commission brought an action in which some of the claims described above are at issue. The Commission has since obtained a preliminary injunction in that case, which continues in litigation. We have been keeping the subcommittee staff advised as to the progress on that case and will continue to do so. As you will recall, the practices involved in that case came to the attention of this subcommittee in hearings last June. Several witnesses appearing before the subcommittee later provided invaluable assistance to the Commission's effort to develop the case and more generally this subcommittee deserves credit for bringing the issue of possible fraud and deception in the infertility area to the attention of the public.

Presently we are continuing to assess the need for additional law enforcement action in the area. As part of our efforts we are continuing to work and we intend to work in the future closely with the subcommittee staff. We are especially interested in obtaining the information that will reveal the extent to which false or unsubstantiated statements are being made to consumers. Toward that end we are looking forward to receiving the data recently obtained by the subcommittee from its survey of over 250 IVF and GIFT clinics.

We intend to remain vigilant against deceptive practices that may exist in this area. I should reemphasize, however, that we cannot be and should not be the sole guardians against abuses in this industry. Because these clinics tend to be small economic units and because there is a wide layer of regulatory authorities that govern the kinds of practices of physicians, that this is an area of shared responsibility and one in which the Federal Trade Commission is playing one part.

For our part we will continue the act of monitoring of those claims. I am glad to report that we have had cooperation in the past, not only from the subcommittee staff, but in the area of medical fraud generally from a number of medical societies, including the American Medical Association and we expect continued cooperation from voluntary associations as well as local and State law enforcement officials.

In summary, I will emphasize the importance of challenging these practices. These hearings have demonstrated and our investigative experience confirms that infertile couples can be subjected to substantial economic and psychological injury, through fraud and deception here, and we remain interested in obtaining information regarding the degree to which providers of infertility services may be engaged in deceptive practices with an eye toward additional potential law enforcement actions.

Thank you for the opportunity to appear before this subcommittee to discuss our activities and I will be most pleased to answer your questions, Mr. Chairman.

[Mr. MacLeod's statement may be found in the appendix.]

[a letter to Chairman Wyden from Mr. MacLeod follows:]

BUREAU OF
CONSUMER PROTECTION

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

April 17, 1989

The Honorable Ron Wyden
Chairman
Subcommittee on Regulation,
  Business Opportunities and Energy
Committee on Small Business
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Wyden:

This letter follows the testimony I provided before your Subcommittee on February 9, 1989. As I noted in my testimony, and recently was highlighted in a separately held briefing between our respective staffs,[1] the Federal Trade Commission has become increasingly active in the area of infertility. These activities have included our investigation of Cecil B. Jacobson, M.D. as well as our activities arising from information provided by sources referred to us by your Subcommittee staff and others.

In an effort to obtain an overview of advertising by infertility services providers, either in the form of brochures or media ads, our regional offices collected print materials and forwarded these materials to our Division of Service Industry Practices ("DSIP"). These promotional materials, along with ads and brochures obtained by DSIP itself, were then reviewed with an eye toward claims about "success rates." Meanwhile, DSIP staff also contacted experts in the field in the hope of supplementing information gathered by FTC staff. As a consequence of these efforts, staff identified several companies that made success rate claims in patient brochures, advertisements or in patient interviews that required further inquiry on our part regarding whether these claims may be misleading consumers as to their chances of achieving success if they enrolled in the program.

Staff's approach begins with two steps. First, companies are contacted to provide clarification and substantiation about claims made. Then, if the response leaves questions unanswered, staff makes a broader inquiry into the company's practices. In addition, we are reviewing other patient brochures and advertisements for a number of companies operating in other states. To the extent that this review reveals potential concerns regarding their advertising, we determine the appropriate action to take with respect to the companies.

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[1] The briefing took place on April 7, 1989 as part of a broader discussion involving health care activities on the part of the Federal Trade Commission since 1975.

Bicentennial of the United States Constitution
(1787-1987)

I trust the foregoing information is responsive to your inquiry at the hearing. I look forward to continued cooperation between our respective staffs in this important area.

Sincerely,

William MacLeod

William C. MacLeod
Director

Chairman **Wyden**. Thank you very much. First, let me say that I have no particular quarrel with you. But I just feel that the Federal Trade Commission has been sleep walking on this issue. This has been a field that has been growing and growing and growing over the last decade. For the agency to say that "they're going to remain vigilant against deceptive practices that exist in this area," seems to me an incredible statement, because to remain vigilant you have got to start being vigilant.

As far as I can tell, and I would like to have this for the record, the Commission has been involved in just one case. The FTC got involved after this subcommittee and television reports and a variety of forums made it public, so the Commission was late, in that one case. I would like to know if any other actions are under way with respect to the infertility area, and if so, when they were begun and what their status is.

Mr. **MacLeod**. Thank you, Mr. Chairman, I think it is important to note the distinction between what the Commission has done on the public record so far and the investigations that the Commission may be undertaking today. As you know the rules of the Federal Trade Commission do not allow us to make public the investigations that we are undertaking unless and until a law enforcement action has resulted from that investigation or the investigation has been closed.

One of our investigations has indeed resulted in law enforcement action, and that one is in litigation. I need, therefore, to be somewhat circumspect about discussing that as well.

Chairman **Wyden**. Absolutely; just tell us numbers and general comments that relate to actions now underway, and we're very much aware of the statutory requirements.

Mr. **MacLeod**. As a matter of fact I can say that a number of advertisements have come to our attention recently and while I cannot reveal to you whether a particular advertisement is under investigation I can tell you that we are now looking at several different advertisements and that those investigations or those inquiries could well lead to some further action in the future.

I should probably describe for you, at least briefly, the means by which we come across leads and information and evidence in this area, and that which will lead us to further law enforcement action. We use a combination of efforts. As you know one of the efforts that we use is that with regard to the staff of Congress, including the subcommittee staff, which has been very helpful to us. We are not everywhere all the time. We do not read every one of the hundreds of millions of advertisements that probably cross the media in any particular year. Neither do we pick out an industry. I don't wake up in the morning and say today is the day I am going after doctors, tomorrow is the day I am going after bankers and next Wednesday it is going to be food producers.

What we do is use a combination of ad monitoring. We do monitor a number of magazines ourselves. We look for tips, we look for complaints, we see ads as a result of a number of public appearances and as a result of publicity, such as is generated by hearings such as these. We expect to have complaints coming in, we expect consumer attention to this issue to lead us to some tips in certain areas.

One of the things that allows us to begin to make determinations about the kinds of claims that we will pursue is the kind of information that this subcommittee has generated. It is not immediately obvious to us, for example, when a particular objective claim is made, whether that claim is a true claim or whether that claim is an exaggerated claim. Once we begin to get a handle on the relevant scientific evidence—for example, the kinds of success rates that one can expect—that is the time that we can begin to look at advertisements and tell from those advertisements whether or not this one merits a closer look, or whether or not this might be an exaggerated claim.

This is the kind of process that we undertake every time we go through all the advertising reviews that we do. Every time we look at an ad, and this is something that nearly every employee of the Federal Trade Commission does, that employee will apply what knowledge he or she has to the industry and determine immediately whether an advertisement is worth another look.

If it's worth another look we will continue to investigate it until we either determine to recommend action or we decide to close down the investigation. So I think that I can describe for you in those general terms a great deal of the activities that the Commission is doing and I think I can tell you that that activity is going to continue. Right now we have three lawyers involved in a litigation that I cannot discuss in great detail. Those lawyers are working hard, and I think they are getting very admirable results as we speak. I think you can expect to see a continuation of this kind of activity from the Commission.

Chairman WYDEN. Let me ask about that continuation. Because I've already talked about that one case. I think that one case is a classic of coming late to the party. That was after it was documented in this subcommittee, it was on television, and for the Commission to say that's an example of aggressive consumer protection is something that I just disagree with completely.

Now I understand the rules that the Commission operates under with respect to specific cases, but why don't you tell us what cities you are looking at from the standpoint of specific advertisements. I would like to know something about specific inquiries now under way.

Mr. MACLEOD. First of all let me explain with regard to whether and how we would bring an individual case, that we will look at the activities that are being undertaken by local authorities and if it does appear that a case might be resolved on the basis of let's say regulatory action by a medical board or some other local action, that might be reason for the Commission to step back and defer its own action until it does determine that action by the Federal Trade Commission is appropriate.

I can tell you in a number of magazines of national nature, of local nature, we have looked at ads both in the local area here, we have looked at ads from other cities throughout the United States. I can cite to you without revealing the particular investigations involved, that we are looking at certain advertisements from down in the Southeast, from the Midwest, from the local area here as well. We are especially interested in those advertisements that cross State lines and that are larger efforts at reaching consumers.

You have to remember that our mandate is for fraud or deception that occurs on an interstate level and in some of the circumstances that we will run into here, we will find an operation that might be more appropriate for regulation at the local level.

Chairman WYDEN. Yes; I still am unclear where specific inquiries are taking place. If you tell me, for example, that a specific inquiry is taking place in Massachusetts, or a specific inquiry is taking place in Florida, that indicates to me that the Federal Trade Commission is moving on a specific case. But as far as I can tell, you are just reading a bunch of newspaper clippings that the subcommittee sends you. Now, could you enlighten me on this and tell me what cities, if any, are the targets of specific inquiries?

Mr. MACLEOD. I can tell you that I think that as far as revealing the nature or the number of Commission formal investigations—that is the kind of information I cannot reveal without a vote of the Federal Trade Commission. I would be glad to provide that for the record. I can——

Chairman WYDEN. Excuse me, you're not allowed to say what cities you are doing specific inquires in? As you know, I sit on the Commerce Committee and we have jurisdiction over the Commission. It was my understanding of the rules that you could not in any way talk about a specific case and I would not wish to seek that information, but that there were no restrictions with respect to cities. Am I incorrect on that?

Mr. MACLEOD. I believe that that is a question that depends in part upon the facts or circumstances. One of the reasons why I am being especially careful here, Mr. Chairman, is that I would be reluctant if the information that I gave to you today identifying some cities combined with other information that the subcommittee has seen today would allow someone to reach a conclusion with respect to a specific investigation we were undertaking.

Chairman WYDEN. Let's do it another way, then. Tell me numerically at this point how many specific inquiries are taking place other than the one well documented case with respect to misrepresentation, false advertising an infertility service. Just a number, that's all I want.

Mr. MACLEOD OK, right now I can identify that there are at least two particular claims by two particular clinics that I am having my people look into in more detail than simply the initial review and the cut that that review should continue. But I should explain to you that this is the kind of thing that can take place throughout the 10 regional offices or in the headquarters of the Federal Trade Commission without coming, necessarily, to my attention.

An attorney reading a magazine or an investigator seeing a commercial on television might indeed conduct a very preliminary investigation without even opening up a formal file and that investigation might never come to my attention. That does not mean that we have not been looking at those particular claims and that those claims have not received some scrutiny and further development by the staff.

Chairman WYDEN. Why don't you submit for the record additional details so that that information can be used in accord with the statutory rules for the business of the Federal Trade Commission.

But we will say for the record then that two additional inquiries, two additional formal inquiries have been made on infertility cases in addition to the one that had been made to date. I appreciate knowing that for the record.

Now you stated because the treatment of infertility generally is practiced by physicians at a local level, consumer protection efforts rest with the State medical boards and offices of the State attorney general. But the State medical boards and practitioners have told the committee that their hands are tied by the Federal Trade Commission and the question of restraint of trade actions by the Commission.

But it seems to me that unless this is resolved, the question of consumer protection is going to fall between the cracks. I would be interested in knowing who is right. Is the Commission right, are the State medical boards right—what is your assessment?

Mr. MacLeod. I do not believe that the antitrust laws pose an obstacle to medical boards or other self-regulatory bodies from policing deception from among their members. The antitrust laws have been used and continue to be used today to prevent activities under the guise of policing deception from accomplishing actual restraints of trade.

But there is no problem under the antitrust laws from a policing of deception that is objective legitimate, provable deception and that is something that we, in fact, encourage voluntary societies and boards to do. The only question under the antitrust laws is when they go beyond that legitimate purpose of policing deception and that is something that the antitrust laws will continue to prevent.

Chairman Wyden. How is there determination, at present, of deception in this area?

Mr. MacLeod. A determination of deception is something that is done according to those broad principles that I laid out a minute ago. Those broad principles once again are whether there is a misrepresentation likely to mislead consumers under the circumstances. Whether a particular representation falls into that category is often a product of a number of facts and circumstances surrounding an individual claim. So we will look, for example, at what kind of claim is made, what evidence there is to back up that claim, and how that claim is perceived by consumers. If the claim is largely puffery then it's not the kind of thing that the Commissioners like to get involved in. When there is a claim of an objective performance characteristic, then that claim is something that we could indeed be looking into further and whether or not we ultimately would be able to prove a deception would depend on many more facts than we could probably describe today.

Chairman Wyden. Do you see evidence that a fair number of clinics are misrepresenting their success rate?

Mr. MacLeod. I think that that is a question that still requires a little more evidence to comment. As I say, I am very grateful for the work that this subcommittee has done here and we are going to be taking that back with us and studying it, and comparing the results that you have discovered with kinds of claims that we have seen.

A number of the ads that we see out there don't claim success rates at all. Then there are ads that do claim success rates, and the subcommittee has heard a great deal of testimony today as to what is the appropriate or what is the inappropriate success rate. Obviously the issue that is most important to us in policing deception against consumers is what does a consumer understand, or what does a consumer take away from a success rate claim when it is made by a clinic? We have heard a number of experts disagreeing over precisely the appropriate numerators or denominators.

One of the questions that we have not fully addressed yet today is what do consumers believe? Is it the embryo transfer, is it the beginning of the cycle? What, when a consumer is told that a success rate is x, y, or z, does the consumer believe to be the denominator or the numerator? That is something that would go into our calculus of whether or not a success rate claim has been deceptive or is accurate.

Chairman WYDEN. But as the consumer advocate, the Commission, do you see anything other than a live birth that would indicate to consumers a measurement of success that's realistic?

Mr. MACLEOD. I think there's no question but that the a birth is the most important factor to consumers. I would not have an objection, however, with a rate that is based on something that consumers fully understand. I would have some difficulty, of course, if someone were to begin representing a success rate based upon pregnancies, with the implication that that rate was equivalent to a rate that referred to live births when in fact because of terminated pregnancies the pregnancy rate is higher. But there is no question that the important factor for consumers is the baby that they can take home.

Chairman WYDEN. Some of the most renowned people in this field have said that consumers are essentially completely in the dark at this point. That they just are not able to get access to good information and to be able to get a handle on what this field is all about. Do you agree with that based on what you now know?

Mr. MACLEOD. I don't think consumers are completely in the dark. I think that there is a growing body of knowledge and information and consumers are learning more. But this is a new industry. So I wouldn't expect the knowledge of this industry to be equal, say, to the knowledge of the success rates of bypass surgery for heart patients. This is something that is very new and it's something that is evolving. I think that we do need to recall or we do need to recognize that there is a role for each stage of the process in the doctor/patient relationship that each stage plays. For example, the advertisement is something that might call attention to this industry, and call attention to this available service. But the whole story is a story that is far more than any advertisement can tell.

I've seen some of the excellent material that has been disseminated by some of the groups here today. Appropriate questions to ask are given in these pamphlets. Even they just give the consumer some of the questions that consumers can use to begin to get the whole story. The ultimate knowledge that will be necessary for a consumer to make an informed decision about this process is the knowledge that that consumer needs to get from a consultation with a physician and the kind of research that is generally appropriate for an expenditure of this level.

Chairman WYDEN. I hope the Commission understands how much confusion and uncertainty there is among American consumers about infertility today. I don't know if you were here, but Dr. Marrs, who is one of most renowned people in the field, said he had a great deal of difficulty going through scientific data and extrapolating out what that information meant with respect to live births. If Dr. Marrs can't do it, it's going to be pretty tough for American families.

I just hope that the Commission will move much more aggressively than it has. Because I'm of the view that it came very, very late to this particular issue and I think we've got to turn this around and move quickly. We must prevent a very promising technology offered by a great many clinics who I think are doing a good job with pioneering medical treatment, aren't brought down by a relatively small percentage of those who are allowed to engage in this hype and misrepresentation and deceit.

So we've got a lot to do and you as the Federal agency that is charged with the responsibility of taking reasonable steps to deal with advertising in the marketplace. That you are going to be right in the center of it. We will be working with you closely.

Mr. MACLEOD. I share your concerns, Mr. Chairman, and you can rely upon a committed FTC.

Chairman WYDEN. Unless you have anything further we'll excuse you.

Mr. MACLEOD. Thank you, Mr. Chairman.

Chairman WYDEN. This brings us to the end of our hearing. The Chair has only a couple of other last observations. This is the Chair's fifth term in the U.S. Congress and during all that time I have not had the opportunity to ever be involved in an undertaking quite like this. I think it is really a pioneering one. I think that through the cooperation of the Fertility Society and a great many very dedicated people, it gives consumers for the first time an opportunity to get a fair shake.

Around our hearing, the people from Government, Dr. Ellis from the Office of Technology Assessment from the profession, Dr. Younger, Dr. Marrs, and others behind me at the podium, Steve Jenning our staff director, Frank Papineau, D. Ann Murphy whose legendary abilities have already been noted, Ernie Ezis, and Mark Balkin, all of my staff, others at the witness table have all made an extraordinary effort. It's an effort that I think is going to make a difference for families.

But there surely is a great deal more to do. There is legislation that needs to be passed, such as what we talked about in the area of embryo lab regulation. There is administrative action that needs to be taken, such as the Federal Trade Commission ensuring that misrepresentation in the market place doesn't rip off consumers. There's voluntary activity that needs to take place, such as what has been discussed with the Fertility Society. The question of some efforts to come up with guidelines in the advertising and ethics area and standardize the definitions of what is success.

So all of us have an extraordinary amount of work to do in this field in the days ahead. We're going to leave the record open at this point because there are some additional submissions that are relevant to the work. But the Chair wants to say thanks to all who have been patient not just today, but for many months, to make this day possible. We will look forward to working with the private sector and with other governmental bodies in the days ahead.

The subcommittee is adjourned.

[Whereupon, at 1:50 p.m, the subcommittee was adjourned, subject to the call of the Chair.]

APPENDIX

Third District, Oregon

News From
Congressman Ron Wyden

2452 Rayburn House Office Building Washington, D.C., 20515 (202)225-4811

OPENING STATEMENT
CHAIRMAN RON WYDEN (D-ORE.)

HEARING ON FIRST NATIONAL SURVEY ON IN VITRO FERTILIZATION CLINICS AND PROCEDURES
MARCH 9, 1989

Today, the Subcommittee on Regulation, Business Opportunities and Energy holds its second hearing on in vitro fertilization and the clinics that promote and perform this treatment.

IVF, the process by which a woman is artificially impregnated with her own fertilized egg, is part of an enormous growth industry. One American couple in five is considered infertile -- that includes an estimated 35,000 married couples in my home state of Oregon. Couples with these problems spend an estimated $1 billion per year on infertility treatments, with $30 million to $40 million spent specifically on IVF procedures.

At our first hearing, the subcommittee was repeatedly told by witnesses that infertile couples find it extremely difficult to obtain clear, understandable and unbiased information about the performance of IVF clinics. Many of these couples are desperate to have children. Some have been on an emotional roller-coaster for years, attempting to conceive through a variety of procedures. They are vulnerable to exploitation and to those who would seek to rip them off.

American families are entitled to the facts. They should be protected from the hype about the fertility businesses.

In an effort to supply these facts, the subcommittee has surveyed 224 clinics across the country doing IVF treatments. These clinics were asked to respond to 28 questions regarding services and success rates. We are releasing those results, today, and the chair will make these observations:

1. Developed with the help of the American Fertility Society leadership, our questionnaire polled 224 clinics, nationwide. One hundred and ninety clinics responded. Of those, 165 said they perform IVF. Twenty-five do not do the procedure. Some 146 clinics provided complete data from 1987 and 1988.

Those clinics conducted 26,332 IVF stimulations in that two-year period, resulting in 20,483 egg recoveries at a cost of $4,000 to $7,000 per procedure. These recoveries produced 2,463 live births.

That's a success rate of about 9 percent.

2. Patient loads are up. These clinics treated 8,167 patients in 1987. In 1988, the figure rose to 10,105.

3. These procedures are being performed in a variety of settings, from giant university medical complexes to single-doctor offices. And the physicians and technicians performing the procedures have vastly differing qualifications. Some of these practitioners have little or no special training in the field.

4. The subcommittee's investigation turned up instances of questionable advertising practices. Success rates are exaggerated, and consumers may be grossly mislead. For example, IVF-Australia of Boston advised us that its IVF program "only recently began full operation." Yet we've seen clinic ads in the Boston Globe touting the "program's" 236 live births. To those of us who know about IVF-Australia, it's apparent that the numbers reflect worldwide experience for this multi-clinic McDonald's of IVF treatment.

The ad makes no mention of the Boston clinic's lack of track record. There is more than an implication that IVF-Australia Boston is producing lots and lots of babies.

5. The Federal Trade Commission has turned its back on the problem of misleading IVF advertising. In their regulatory slumber, the FTC's policy with respect to IVF has been little more than "let the buyer beware." Much more must be done by the commission, which is charged with truth-in-advertising enforcement, to protect couples from slanted or irresponsible advertising.

6. At present, there is virtually no professional or government oversight of this booming industry. Any practitioner can hold himself out as a fertility specialist. Embryo labs are exempt from even the cursory inspections required at other medical laboratories. The problem has grown so serious that one of the foremost doctors in the field -- Dr. Richard Marrs of the Institute of Reproductive Medicine in Los Angeles -- has said that the IVF business will self-destruct without some form of government regulation.

In 1987, the Office of Technology Assessment reported that over half of the fertility clinics then operating had failed to produce a live birth. Today, for the first time, couples can obtain clinic-specific information on the majority of IVF practitioners.

But the chair urges caution on the use of this data.

Success rates should not be viewed in a vacuum. Just as they can be abused to give patients false hopes of success, they can be misused to give them a falsely dismal view of IVF's successes. For example, clinics who treat the more difficult cases such as male infertility and older women can reflect lower success rates. But they may be the very clinics some patients need to treat their specific problems. Others -- who carefully select patients most likely to conceive -- can show very high success rates, but would be of little value to patients whose inherent infertility problems are by nature harder to treat.

This survey can help Americans make more informed choices. We hope it will be a roadmap to help them ask the right questions, and to enable them to read between the lines and fill in the blanks left by the clinics themselves. Under the best of circumstances, infertile couples face a number of invasive medical procedures, the risk of dangerous complications, and large medical bills.

Frustrated couples, some at the emotional breaking point, are entitled to a fair shake and the plain facts. This subcommittee will continue to work until such simple justice is done.

Now, I'd like to welcome our first witness. Ms. Jo Beth Williams is an actress familiar to many of us. She is also the honorary chairwoman of National Infertility Awareness Week, which is coming up this October. Ms. Williams, I want to thank you for being with us today. We know that these are painful and very private issues and we very much appreciate your willingness to share your experiences with us. Without the courage of people like yourself our job here would virtually impossible.

REGULATION OF THE ADVANCED REPRODUCTIVE TECHNOLOGIES

TESTIMONY FOR

UNITED STATES CONGRESSIONAL SUB COMMITTEE

ON

REGULATION AND BUSINESS OPPORTUNITIES
B-363 RAYBURN HOUSE OFFICE BLDG.
WASHINGTON, D.C. 20515

MARCH 9, 1989

BY

JO BETH WILLIAMS

Congressman Wyden, I greatly appreciate what this committee is trying to do. All of us who want so much to have a baby and must face the specter of infertility are extremely vulnerable. We will do anything, try any treatment, and believe what our doctors tell us trustingly, because we are desperate. That is why I wanted to come here today and tell you of my experiences. I have heard and read horror stories about infertile couples being taken advantage of by unscrupulous doctors. Mine is not such a case, but I think it is a much more common story.

My name is Jo Beth Williams, and I am an actress. Eight years ago, my husband and I decided we wanted to have a baby. We assumed that when we stopped using birth control, the most natural process in the world would occur--pregnancy. When it did not happen the first year, my gynecologist assured me it would happen soon, and I believed him. After all, our careers sometimes separated us; so we were not together every month. After two years, my doctor suggested I take my temperature every morning and keep a chart of my cycle--difficult to do, and something I was never sure I was doing correctly, but I did it for the next 5 years. Sex was now timed around that temperature chart--inconvenient, not terribly romantic, but not yet desperate. My doctor did not tell me that if, after six months of trying, one hasn't conceived, you are considered to have fertility problems. The third year I had a laparoscopy, and no apparent abnormality was found. Although my doctor and I had not discussed the problem as "infertility", I knew something was wrong. I felt, after three unsuccessful years of being told to "relax, be patient and it will happen", it was time to find an infertility specialist.

The problem was, I did not know how to find such a doctor. All gynecologists, including my own, claimed to handle infertility. My only recourse was the recommendations of friends. Soon, over the next two and one-half years, I tried several gynecologists who said they also did infertility. I continued charting my temperature, tried the ovulation tests when they came out, and took estrogen for awhile. My husband had sperm tests. By the fifth year, we were doing monthly vaginal inseminations. Sex had become me racing to the doctor with my husband's sperm in a jar, not about spontaneous feeling.

We began to wonder if the dream we shared--to have a baby--was going to kill our marriage. We did not know why we were not getting pregnant. No one could give us any answers, and no one offered any comfort or solution, except to "relax and not think about it". This, of course, was impossible, because by the sixth year I would cry every time I saw a mother and baby and felt angry and jealous when I saw a pregnant woman. When several of our friends became pregnant, we found it impossibly painful to be around them.

My sense of failure was so strong that I began to feel I must be guilty of something terrible, that I was being punished, but I did not know for what. That I could not do the very thing my body was designed to do--conceive and carry a child--must mean that I was not fully a woman, I felt. All my other accomplishments in life seemed to fade into the background in the face of this failure. Every other woman seemed able to do it so easily, and I could not. I cannot express the ache I felt to have a baby, to hold my own baby, and the emptiness I felt not having that. I grew to hate my body. Every month when I got my period, I would cry and become despondent. My husband would try to cheer me up, but I knew underneath he was hurt and angry each month, also. Ironically, during those years, I was often cast as mothers and "gave birth" twice on film--a little Hollywood joke.

A sense of hopelessness began to creep into our lives. We did not know where to turn. Because we felt like failures, we did not feel comfortable discussing our problem with relatives and friends. I did not then know of the existence of Resolve, an organization to help infertile couples. Fortunately, we became friends with another couple who were having similar problems, and through them, I finally found a doctor who did specialize in infertility. This was after six years of trying to get pregnant. With each year I grew older, heard the biological clock ticking louder and became more and more desperate, afraid that if we kept trying and failing, we would eventually be too old to be ideal adoptive parents.

When I found this infertility specialist, I felt such relief, because he so clearly understood what we were going through. He sent me to a counselor to talk about it, which lifted some of the emotional weight I had been carrying. After a few months of uterine inseminations, I had surgery to remove nine fibroids from my uterus.

Four months later, a miracle occurred--I became pregnant. My husband and I were ecstatic. It was like a dream. I fell in love with every baby I saw. I glowed. I went into every baby store to look at the little clothes, and we began to think of names. At eight weeks we had the joy of seeing our baby's heartbeat on a sonogram. At twelve weeks, during a routine sonogram, the radiologist informed us that the baby had died. No one knew why. These things just happen. Staring at that image on the screen, of our little dream which had died, we began to cry and hold each other, whereupon we were asked to leave the room to allow the next patient in. I immediately had a D & C and felt as if my heart had been cut out as well as my pregnancy. Over the next few months, I wondered if I might lose my mind.

My infertility specialist sent me to see the man he felt had the best in vitro program in Los Angeles. This doctor told me his results statistics; so I went in knowing pretty much what our chances were. I had no great expectations, but I carried secret hope in my heart, that little seed of hope that never seems to completely die when you want to have a baby. I was extremely fortunate to have found this in vitro program. This doctor was caring, concerned and positive without building false hope. We did the GIFT procedure, and to my surprise, I got pregnant again. I began to have spotting very early, however; so it was not a shock when it became apparent that it was a tubal pregnancy. I was one of the unlucky one or two percent of women doing GIFT who had ectopic pregnancies.

After this second loss, we decided to try to adopt, and now we have a beautiful baby boy. However, we have decided we want another child, and we are planning to give GIFT or in vitro another try. As I said, that seed of hope never dies.

I wanted to tell you my story, because in a way, I have been lucky. I was fortunate to have had enough money to pay for very expensive procedures, much of which is not covered by insurance. Also, I did eventually find people who could help me, although it took me six years and trying numerous doctors to do so. But I live in a large metropolitan area, and even I had a very difficult time getting the kind of information I needed about who could really help me.

I have friends and relatives who are having fertility problems. I know how desperate and vulnerable they are. You will try any treatment, pay large sums of money, listen to anyone who says they can help you. The drive to have a baby is that strong.

All the doctors I dealt with were honest, kind men, but I felt they should have been more open about their limitations and referred me to others who could really help me. The years were slipping away, and the age factor is a vital one in infertility. I have heard true horror stories from friends about unnecessary surgeries, huge fees, doctors who cannot even remember their patient's names after years of treating them, etc. I believe it is cruel to put people who are already emotionally battered in the desperate position of not knowing how to fine the right care. There must be ways to protect us, to make information available to us. We, the infertile couples, need to learn what questions to ask, and we need to know where we can get the right answers.

Testimony of Ann Petter, Executive Director
RESOLVE, Inc.
5 Water Street
Arlington, MA 02174

Given before the Small Business Administration Committee
United States House of Representatives
March 9, 1989

RESOLVE is a non-profit organization incorporated in 1974 dedicated to providing emotional support, referrals, information, education and advocacy for the infertile population. We are a membership organization supported primarily by membership dues, literature sales, and direct mail solicitation to our members and friends. We represent over 15,000 people in 51 chapters from Maine to Los Angeles. The chapters specialize in telephone response, professionally led support groups, informational symposia and workshops while the national office maintains lists of surveyed infertility specialists and medical contacts throughout the United States and produces widely acclaimed informational fact sheets on a range of topics such as "What is an Infertility Specialist?", "Male Infertility" and "Private Adoption." Our intent is to inform patients (a.k.a. consumers) so that they may make informed choices.

In fact, one might consider us a consumer advocacy organization. And as a consumer advocacy organization we are concerned with the level of trust between the consumers and vendors or, in this case, the patients and the medical practitioners.

2-Testimony: Petter, RESOLVE, Inc.

The difference between a patient seeking medical help and any one of us and the dishwasher salesperson is that the patient, by virtue of his/her medical situation is suffering from anxiety which may make him or her extremely susceptible to false hopes and misinformation. In the case of the appliance purchaser, many regulations have been made to equalize the participants and to reduce the anxiety which may be present when one party knows considerably more about the subject at hand. When infertile people decide to purchase the services of an IVF clinic, they probably have been through years of infertility tests and procedures. They face a procedure which they may consider their last hope to have a biological child, a procedure which will further drain them physically, emotionally and financially. In a word, they are vulnerable.

Let me quote from two recent letters to the editor in our newletter:

> "I have undergone four unsuccessful IVF attempts....As a person who has weathered the poor success rates, the pain, and the emotions described...(including a cycle in which five eggs were retrieved and did not fertilize).... prospective IVF couples...are unprepared for the emotional roller coaster and let down. As painful as these realizations are, it is far more painful and harmful to enter into this imperfect procedure with unrealistically high expectations....only those people involved in IVF can comprehend the devastation that an unsuccessful outcome can bring, especially if their hopes have been unrealistic....My IVF clinic

> advised me to 'try IVF until it worked.'"
>
> "[I am] an infertile woman who has undergone
> 5 IVF attempts and speaking on behalf of
> other couples with 'typical' IVF experiences,"
> [Easy experiences are not the norm]
> "Although optimism and hopeful messages are very
> important to all infertile people, it's equally
> as important to balance these messages with realism.
> No mention was made of IVF's extreme emotional
> pressures and financial burden." [Referring to a
> previous article]
> "IVF is hope blended with the heavy burden of
> despair and loss for most of us, and it is best to
> try to prepare hopeful IVF candidates realistically
> for this bittersweet experience. Current IVF clinics'
> success rates tend to conceal reality, and we had
> hoped that RESOLVE could do better."

I could, of course, go on at great length about the calls we receive about IVF and how very difficult it is for people and how confusing and how frightening when they feel that they cannot trust the information they are receiving about this perceived answer to their problems.

RESOLVE is concerned about their confusion and about the potential for misleading them as well as other problems which IVF clinics as patient or profit driven medicine may produce. To alleviate some of these problems we propose the following suggestions.

First, we would like to see the American Fertility Society develop some standards for IVF clinics and, to allow for new clinics to open, also special standards for provisional clinics. AFS is well able to develop these standards without much outside assistance; however, we would like to recommend one or two things. It is very easy for both physician and patient to lose sight of the ultimate goal. High tech reproductive techniques are exciting—so exciting that everyone may forget about the baby which is the whole impetus behind this effort. We suggest that after several IVF attempts an outside referral be made for counseling the IVF patient. In-house counseling is fine for support while the patient is dealing with the rollercoaster of emotions which IVF engenders; but when it comes to a decision to move on, objectivity will be needed. If this could be incorporated into the standards for IVF clinics and programs, it would increase the patient/public's belief in the trustworthiness of the medical facilities providing the procedure.

Enforcing these standards may be difficult if not impossible; the crucial thing is that they be made public so that the consumer can ask the appropriate questions and can evaluate the answers.

Second, the labs need to be licensed. Since this is one of the most important pieces of in vitro fertilization, the labs certainly should be subject to at least as rigorous inspection and regulation as your average dental lab.

Most importantly, RESOLVE would like to see truth in advertising from the IVF clinics. We have heard of clinics quoting the national statistics rather than their own in their promotional material. While this is unusual, it is certainly difficult to ferret out the "take home baby" rate of any clinic or program. Number of babies compared to what— number of women who are enrolled in the program, number of stimulation cycles, number of transfers?

Let me quote again from RESOLVE's newsletter (December 1988) from an article by Machelle M. Seibel, M.D. originally printed in the August 1988 Obstetrics and Gynecology:

> "A couple recently came into my office and the wife asked me, 'Doctor, we are looking for the best IVF program. What is your success rate?'"
> "I said, 'I want to tell you the whole truth.'"
> "'What do you mean?' she replied. 'Doesn't every IVF program tell the whole truth?'"....
> "'I am confident,' I said, 'that doctors and IVF team members do not lie. The problem is mathematical. ....You see, every fraction has a numerator and a denominator. In IVF the numerator is the number of pregnancies....'[pregnancies or babies?]
> 'All pregnancies do not result in babies in a fraction of the truth....The numerator may represent a positive pregnancy test or a term pregnancy'...I continued my discussion of a fraction of the truth by talking about the denominator. 'The denominator,' I said, 'is even more confusing to explain. It can represent patients, oocyte retrievals, or embryo transfers.'

> [For example] 'Let's pretend a new IVF clinic has one patient who goes through the procedure five times. The first time they fail to retrieve an egg, and the second time the retrieved eggs fail to fertilize. The last three cycles result in embryo transfers and the patient conceives on her fifth attempt. What is the success rate?'
>
> "The patient responded, 'The IVF success rate is one pregnancy per five oocyte retrievals or 20%, one pregnancy per three embryo transfers or 33%, or one pregnancy per one patient or 100%, depending on which denominator you use.'
>
> 'That's right!' I told her, 'but don't forget about the numerator in a fraction of the truth....[Also] They are time and patient selection. You see, if IVF success rates represent only a particularly successful interval of time, the results will seem higher. Results will also seem increased if they exclude older patients or men whose sperm counts are extremely low,' I explained."

Wanting to put your best foot forward is very human; and, in this success oriented culture, it is understandable that IVF clinics and programs want to sound successful. However, what they are doing is obfuscating. It is almost impossible for a lay person to decipher the claims of many of the programs. It is essential that prospective patients know what their chances are not only to conceive but to achieve their ultimate goal—a baby. If a woman is the ideal candidate, it would be hard to discern her real chances. Relating the data to her own diagnosis or age may be even more difficult. The impact of one's diagnosis on the success rates should be clarified at the very start for each and every prospective IVF participant. "What is your diagnosis and your age?" should be one of the primary questions an applicant is asked.

In short, we are asking for truth in advertising, for fairness. IVF, GIFT, other high tech procedures are clearly patient driven medicine which is sometimes synonymous with profit driven medicine. RESOLVE knows that to establish a new clinic is costly: malpractice insurance is high, salaries for highly trained personnel are up, rent and equipment are expensive—these costs must be covered; however, not at the expense of the patient nor of medicine's good name. Let us re-establish the trust by giving out clear, comprehensible and truthful information.

STATEMENT

of

THE AMERICAN FERTILITY SOCIETY

on

IN VITRO FERTILIZATION CLINICS

Presented by

J. Benjamin Younger, MD

before the

Subcommittee on Regulation and Business Opportunities

House Committee on Small Business

March 9, 1989

Mr. Chairman, Members of the Subcommittee, my name is J. Benjamin Younger, M.D. I am an obstetrician-gynecologist who specializes in endocrinology and infertility. I am Professor and Vice Chairman of the Department of Obstetrics and Gynecology at the University of Alabama Medical Center in Birmingham. I am also President of the American Fertility Society (AFS), an organization of almost 11,000 members interested in disorders of the reproductive system. It is in this role that I address you today.

I am pleased to be here as the Subcommittee unveils the data from their survey of clinics that practice in vitro fertilization (IVF) and gamete intrafallopian tube transfer (GIFT). Our organization worked with Chairman Wyden and his staff to develop this clinic questionnaire and analyze the survey results. A common goal of the Subcommittee and the AFS is to provide accurate information to patients. We believe the availability of this data will assist patients in making an informed choice when selecting an in vitro fertilization program, and over the long-run, will improve patient care.

Our involvement in this project began last June when the American Fertility Society testified at a hearing on infertility held before this Subcommittee. At the AFS Board of Director's meeting on October 7, 1988, Dr. Alan DeCherney, then President of the Society for Assisted Reproductive Technology (SART), an affiliate of AFS, related to the Board various communications he had had with Chairman Wyden's office. Other members of the Board also presented the interaction that they had had with various Members of Congress concerning issues related to the care of the infertile couple, and in particular, in vitro fertilization and related technologies. Following this discussion, the Board requested that I as the incoming President, along with

Dr. DeCherney, immediate past president of SART and new member of the AFS Board of Directors, Dr. Edward Wallach, a past president of AFS and Chairman of our Ethics Committee, along with the current president of SART, Dr. Martin Quigley, come to Washington to meet with Chairman Wyden and his staff to explore ways that AFS could assist in the collection of data concerning the current practice of IVF and GIFT, and to assist in the interpretation of that data.

After the Washington meeting, this group of individuals worked with Chairman Wyden to develop a questionnaire that was sent to all individuals or programs which were providing, or at least had expressed the intent of providing, IVF and GIFT services. The American Fertility Society supplied Chairman Wyden's office with a list of IVF programs that were members of SART, reported to the IVF Registry, or programs that had come to the attention of the Society, but were not engaged in the aforementioned activities. The IVF Registry is an ongoing collection of IVF and GIFT data from voluntary participating programs coordinated by AFS, SART, and Medical Research International. The committee staff then provided an even larger list of names of people or programs supposedly active in IVF/GIFT. I sent a letter to each of these programs or individuals informing them about the pending survey and encouraging them to respond. In all, I sent out 260 letters. Responses began to come in slowly, but surely, and I sent out a second letter in January which encouraged those that had not done so to promptly respond. I sent out 96 of these second letters. Almost all active programs have either responded or indicated that their data will be immediately forthcoming. Working with Chairman Wyden's staff, we have identified programs that are no longer in existence. We have also found that many of the names on the list represented individuals with an interest in, but not actively performing IVF. While the response is not absolutely complete, I believe that the information now available is indeed an accurate reflection of the current practice of IVF and GIFT in the United States.

Both the American Fertility Society and the Society for Assisted Reproductive Technology are voluntary organizations committed to the provision of high quality health care. The AFS is primarily an educational organization dedicated to advancing knowledge about infertility, reproductive endocrinology and biology, and conception control. Almost 80% of the 11,000 members are obstetrician-gynecologists. The remaining 20% of the membership consists of urologists, basic scientists, and other individuals participating in the care of people with disorders of the reproductive system. Membership in AFS is open and confirms interest in these particular areas, rather than expertise. The AFS has established minimal standards for programs of IVF and GIFT. A copy of these standards is attached.

The AFS has three affiliated societies that do not have open membership. One of these is the Society for Assisted Reproductive Technology. An application for membership in this organization is attached. Both IVF programs and individuals can become members of SART. Programs must meet the AFS minimal standards and demonstrate success in producing pregnancies. Minimal performance requirements are three deliveries resulting in live births, and the performance of a minimum of 40 cycles in a given year. For an individual to be a member of SART, he or she must be a team member of a SART program.

All members of SART must report their results to the IVF Registry which was previously described. Participation for other programs is voluntary, and not all IVF programs report their results to the IVF Registry. Registry results are published annually in the January issue of the AFS Journal, Fertility and Sterility. Membership in SART, which requires programs to meet certain standards and produce babies, is one factor that patients can consider when selecting an IVF program.

In evaluating the success of an in vitro fertilization program, I believe that it is important to first have an understanding of the natural pregnancy rate that can be expected from reproductively normal couples. Understanding this is important so that patients undergoing IVF can develop realistic expectations about outcome. It is not reasonable to expect that every IVF attempt will lead to pregnancy since this does not occur in the natural process. Therefore, I would like to review with you the efficiency, or perhaps a better term is inefficiency, of the human reproductive system.

It is generally accepted that reproductively healthy couples desiring to conceive will do so at about the rate of 25-30% per month. This rate is derived from the use of sensitive and sophisticated tests similar to those used in monitoring the IVF patient. In these naturally occurring pregnancies, approximately 30% will terminate in miscarriage within the first three months. Some literature reports a lower pregnancy and miscarriage rate. This is because less sensitive methods of pregnancy detection were utilized in those studies. Once a pregnancy progresses beyond three months, there is a slight chance that further pregnancy loss will occur. The bottom line is that in reproductively normal couples desiring to conceive, the best that can be expected is approximately a 20% chance that the couple will have a baby as a result of a single months attempt to do so. It should be remembered that IVF patients are not reproductively normal!

IVF is a last resort effort, and provides hope for some couples unable to conceive otherwise. Data from the 1987 IVF Registry with 96 clinics reporting reveals an average take-home baby rate of 11%. Data from the survey under discussion today confirms that take-home baby rate from an IVF procedure in 1987 to be 11%. 1988 data suggests that that rate will be at least 13%. We recognize that this average does not yet approach 20%, but in many ways might be considered remarkable in view of the fact that there has been no Federal support for research in this area. We believe that research is a key factor for improving results.

As stated previously, the AFS is primarily an educational organization, and in the past we have focused on the education of our members. As the Society has grown and developed, it has become apparent to us that we should expand our role and interact to a greater degree with the public. In the past year, we have begun to produce patient information brochures which can be distributed to patients by their physicians or obtained from AFS. We are pleased to announce that we now have a pamphlet entitled "Questions to ask about an IVF or GIFT Program" which can be obtained at no cost by individuals about to enroll in an IVF or GIFT program. A copy of the pamphlet is attached for your review. The pamphlet outlines important points that individuals should investigate when selecting an IVF program. These include the qualifications and experience of personnel, the types of patients being treated, support services available, cost, convenience, and success rates. This pamphlet was developed from information contained in an about to be published brochure entitled "IVF and GIFT: A Patient's Guide to Assisted Reproductive Technology". This, too, will be available to physicians and their patients.

Finally, I would like to comment on the lack of Federal support for research related to the new reproductive technologies. As you know, the discontinuance of the Ethics Advisory Board (EAB) in 1980, has in effect prohibited the National Institutes of Health from conducting or supporting research in this area. Last fall, the Assistant Secretary for Health, Robert E. Windom, M.D., announced that the Department of Health and Human Services would re-establish the EAB. This has not yet been accomplished, and we call upon you to urge the new Administration to follow through on this announcement. The AFS also calls upon you to support additional funding for reproductive health research. Much remains unknown about the causes of infertility. Increased funding for basic biomedical research could lead to the discovery of additional causes of infertility and possible avenues of treatment. Research could also lead to improvements in the new reproductive technologies such as in vitro fertilization.

In conclusion, the American Fertility Society is dedicated to expanding its educational role to better serve our members, patients, and the public-at-large. We hope that by providing better information and better education, patients will be able to make better choices.

I will be pleased to answer any questions.

COST AND CONVENIENCE

1. How much does the entire procedure cost, including drugs, per cycle?
2. Do I pay in advance? how much?
3. What are the modes of payment?
4. If applicable, will you submit any bills to my insurance company?
5. How much do I pay if my stimulation cycle is cancelled before egg recovery? before embryo replacement?
6. What are the costs for embryo freezing, storage, and transfer?
7. How much work will I miss? my husband miss?
8. What types of counseling and support services are available?
9. If I must have lodging, is there a low-cost place for me to stay? Do you help arrange this?
10. If I do not get pregnant, when do I make my next office visit for further evaluation and counseling.

The following acronyms and terms are used in this pamphlet:

AFS (The American Fertility Society). An organization of health care specialists interested in reproductive medicine.

GIFT (gamete intrafallopian transfer). The direct transfer of a sperm/egg mixture into the fallopian tube. Fertilization takes place inside the fallopian tube.

IVF (in vitro fertilization). An egg and sperm are combined in a laboratory dish where fertilization occurs. The fertilized and dividing egg is transferred into the woman's uterus.

IVF Registry. An ongoing collection of IVF results from voluntarily participating programs coordinated by the AFS, SART, and Medical Research International.

PROST (pronuclear stage tubal transfer). Egg is fertilized in a laboratory dish and transferred to the fallopian tube before cell division has occurred (pronuclear stage).

SART (the Society for Assisted Reproductive Technology). An affiliated society of the AFS comprised of programs that have demonstrated their ability to perform IVF and GIFT.

TET (tubal embryo transfer). An early stage embryo is transferred to the fallopian tube.

ZIFT (zygote intrafallopian transfer). Egg is fertilized in vitro and the zygote (undivided but fertilized egg) is transferred to the fallopian tube.

This pamphlet presents a partial listing of questions to ask about an IVF/GIFT program. See your physician for further guidance.

For additional copies of this pamphlet, send a self-addressed, stamped business-size envelope to:
The American Fertility Society
2140 11th Avenue South, Suite 200
Birmingham, Alabama 35205-2800

Prepared by The American Fertility Society in conjuction with SART.

SART
1988

QUESTIONS TO ASK ABOUT AN IVF/GIFT PROGRAM

Excerpts from
IVF & GIFT - A Patient's Guide
to Assisted Reproductive Technology

THE AMERICAN FERTILITY SOCIETY

SELECTING AN IVF PROGRAM

When selecting an IVF/GIFT program, information is crucial. Important points to investigate include the qualifications and experience of personnel, types of patients being treated, support services available, cost, convenience, and success rates.

It should be remembered that IVF and GIFT are two separate techniques, and the types of patients accepted into either program influences success rates. Couples over 40, and those with male factor infertility, are less likely to get pregnant than younger couples faced with tubal disease, minimal endometriosis, or unexplained infertility. GIFT is most often used for couples with unexplained infertility and minimal endometriosis and, therefore, may result in a higher pregnancy rate due to the types of patients being treated.

Cryopreservation (freezing) of embryos is available in some IVF/GIFT programs. This offers the possibility of pregnancy beyond the initial treatment cycle. In rare instances a patient can benefit from donor sperm or eggs. In addition to IVF and GIFT, some programs offer other procedures such as combined IVF-GIFT, ZIFT, PROST, TET, etc. These procedures can be considered similar to GIFT.

Older programs have had the opportunity, to treat more patients and may have a higher success rate. Although new programs have not yet established long-term success rates, their personnel can be equally qualified. New programs are being established across the country, often in a location more convenient for you.

Credibility is important, too. Does the program adhere to AFS minimal standards? These require IVF/GIFT programs to have on-staff personnel trained in reproductive endocrinology, laparoscopic surgery, sonography, hormone measurement, tissue culture technique, and sperm/egg interaction. Does the program report results to the IVF Registry? Participation is voluntary in this ongoing collection of IVF/GIFT results. The compiled results are published annually in the AFS journal, *Fertility and Sterility*.

The above considerations and answers to the following questions, which focus on a program's recent performance, will help you make an informed decision when choosing an IVF/GIFT program.

SUCCESS RATE

1. When did this program perform its first IVF procedure? first GIFT procedure?
2. How many babies have been born from this program's IVF efforts? GIFT efforts?
3. In the past two years, how many stimulation cycles have been initiated for IVF? for GIFT?
4. In the past two years, how many egg recovery procedures have been done in the IVF program? GIFT program?
5. In the past two years, how many embryo transfer procedures have been done in the IVF program?
6. In the past two years, how many pregnancies have resulted from IVF? from GIFT?
7. In the past two years, how many miscarriages have occurred from pregnancies initiated by IVF? by GIFT?
8. For the past two years, how many live births have occurred in your program from IVF? from GIFT?
9. How many ongoing pregnancies are there from IVF? from GIFT?
10. How many deliveries were twins or other multiple births?

Programs define success in various ways. To most, success is a baby, not a pregnancy. Here are three ways to determine the "take-home baby" rate. The first two equations are based on egg recovery procedures and the third is based on embryo transfers. For IVF or GIFT, divide live births (question 8) by egg recovery procedures (question 4); or, add live births (question 8) to ongoing pregnancies (question 9) and divide the sum by egg recovery procedures (question 4). In the latter equation, which can be applied to the most recent results of a program, you are assuming the ongoing pregnancies will result in live births. For IVF, divide live births (question 8) by embryo transfers (question 5).

DETAILS ABOUT THE PROGRAM

1. Does the program meet AFS minimal standards?
2. Does the program report its results to the IVF Registry?
3. Is the program a member of SART?
4. How many doctors will be involved in my care?
5. Is one or more doctors board certified in Reproductive Endocrinology?
6. To what degree can my own doctor participate in my care?
7. Whom do I call day or night if I have a problem?
8. Do you freeze embryos (cryopreservation)?
9. Is donor sperm available in your program? Are donor eggs?
10. Do you have an age limit?

(over)

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Minimal standards for programs of in vitro fertilization

American Fertility Society*†

I. *General Considerations*

Every group initiating a program of in vitro fertilization should have all aspects of the program approved by a properly constituted Institutional Review Committee. The Institutional Review Committee or its equivalent should ensure that a record is kept of all attempts made at securing pregnancies by these techniques. The records should include all medical aspects of the treatment cycles and a record of success or failure with respect to oocyte recovery, fertilization, cleavage, conceptus transfer, biophysical monitoring of fetal growth, pregnancy outcome, and complications. These institutional records, which should be separate from the regular records of the medical institution, should be confidential. Summaries for statistical purposes, including details of any congenital abnormalities among offspring, should be available for correlation.

It is recommended that special attention be given to the emotional needs and the emotional support of these patients.

It is recommended that the director of the program have clinical experience and competence.

In view of the many research opportunities offered by programs of in vitro fertilization, it is urged that all programs be designed to take advantage of these opportunities.

II. *Personnel*

Personnel with the following four types of skills are required as a minimum. A single individual may possess one or more of the required skills.

(1) An individual with the experience and training required for board certification in reproductive endocrinology. While individuals with equivalent training and experience are certainly acceptable, board certification clearly indicates that the required skills in reproductive endocrinology have been obtained.

(2) A pelvic reparative surgeon with laparoscopic experience with evidence of specialized training in follicular aspiration.

(3) An individual experienced in male reproduction (andrology) with special competence in semenology.

(4) An individual with knowledge of and practical experience in tissue culture, gamete maturation, fertilization, and early zygote cleavage in human and animal systems.

III. *Special Services and Facilities*

These services and facilities must be on call on a daily basis with 24-hour availability.

(1) Ultrasonography.

(2) Hormonal assays.

(3) Facilities for follicular aspiration and conceptus transfer.

(4) Anesthesia.

(5) A laboratory for gamete fertilization and conceptus development near the operating room with two-way communication between the laboratory and operating room.

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*Report of an ad hoc committee of The American Fertility Society: Howard W. Jones, Jr., M.D., Chairman, Anne Colston Wentz M.D., Martin M. Quigley, M.D., Richard P. Marrs, M.D., and C. Alvin Paulsen, M.D. Approved by the Board of Directors of The American Fertility Society.

†Reprint requests: The American Fertility Society, 1608 13th Avenue South, Suite 101, Birmingham, Alabama 35256.

Minimal standards for gamete intrafallopian transfer (GIFT)

The American Fertility Society

Birmingham, Alabama

In January 1984, The American Fertility Society (AFS) published minimal standards for in vitro fertilization and embryo transfer.[1] The society has received numerous requests for similar standards for gamete intrafallopian transfer (GIFT). These requests have originated from hospitals, insurance companies, legislative committees, and a state insurance commission. In response to this, the AFS has drafted, in consultation with the Society for Assisted Reproductive Technology and the AFS President's Executive Council, the following minimal standards. These have been approved by the Board of Directors of The American Fertility Society as of April 8, 1988.

Minimal Standards for Gamete Intrafallopian Transfer

Gamete intrafallopian transfer (GIFT) may be considered a standard clinical procedure provided:

A. The patient and her partner have been investigated using as a minimum the standards established by The American Fertility Society.
B. The patient has at least one normal fallopian tube and a condition not amenable to less invasive techniques.
C. The facility has a gamete laboratory and personnel that meets The American Fertility Society minimum standards for an in vitro fertilization program.

It is preferable that GIFT be performed in a facility that is prepared to carry out in vitro fertilization as an alternative in the event that during the procedure GIFT proved to be not feasible.

REFERENCE

1. American Fertility Society: Minimal standards for programs of in vitro fertilization. Fertil Steril 41: 13, 1984

Reprinted from Fertility & Sterility
Vol 50, No. 1, July 1988

The American Fertility Society, 2140 Eleventh Avenue South, Suite 200, Birmingham, Alabama 35205-2800

SOCIETY FOR ASSISTED REPRODUCTIVE TECHNOLOGY APPLICATION FOR MEMBERSHIP

DATE ____________________

I. **Name of Center:** ____________________
Affiliated University/Institution (if different): ____________________
Program Director: ____________________
Address: ____________________
____________________ Phone: ( ) ____________________

II. **Names of all IVF team members who are regular AFS members**
____________________ Date of AFS Membership ____________________
____________________ Date of AFS Membership ____________________
____________________ Date of AFS Membership ____________________
____________________ Date of AFS Membership ____________________
____________________ Date of AFS Membership ____________________

III. Certification of Compliance with the American Fertility Society Minimum Standards for Programs of In Vitro Fertilization (Fertility and Sterility 41:13, 1984)
Personnel (one person may fill more than one requirement): ____________________
Reproductive Endocrinologist: ____________________
Pelvic Reparative Surgeon: ____________________
Andrologist/Semenologist: ____________________
Embryologist: ____________________

IV. **QUALIFICATIONS OF KEY PERSONNEL** (a current Curriculum Vitae must be attached for each person)

1) **REPRODUCTIVE ENDOCRINOLOGIST**
Name: ____________________
Address: ____________________
____________________ Phone ( ) ____________________
Sex: __________ Social Security # ____________________ Citizenship ____________________
Date of Birth: ____________________ Place of Birth: ____________________
Year Passed American Board Ob/Gyn Regular Written Exam: __________ Oral: __________
Year Passed American Board Ob/Gyn Reproductive Endocrinology Written Exam: __________ Oral: __________

Medical School
Dates: ____________________ Degree: ____________________
Internship
Dates ____________________ Specialty: ____________________
Residency
Dates ____________________ Specialty: ____________________
Fellowship in Reproductive Endocrinology
Dates: ____________________ ____________________
Other Postgraduate Training (6 months or more)
Dates: ____________________ Specialty: ____________________

Clinical Practice in Reproductive Endocrinology (most recent first): ____________________
____
____
____

Academic Appointments (most recent first): ____________________
____
____

Specialized Training In Assisted Reproductive Technology:

Description of Current Practice:

IV. QUALIFICATIONS OF KEY PERSONNEL (a current Curriculum Vitae must be attached for each person)

2) **PELVIC REPARATIVE SURGEON**

Name:
Address:
Phone ( )
Sex: Social Security # Citizenship
Date of Birth: Place of Birth:
Year Passed American Board Ob/Gyn Regular Written Exam:
Year Passed American Board Ob/Gyn Regular Oral Exam:
Year Passed American Board Ob/Gyn Reproductive Endocrinology Written Exam:
Year Passed American Board Ob/Gyn Reproductive Endocrinology Oral Exam:

Medical School
Dates: Degree:

Internship
Dates Specialty:

Residency
Dates Specialty:

Fellowship in Reproductive Endocrinology
Dates:

Other Postgraduate Training (6 months or more)
Dates: Specialty:

Clinical Practice in Reproductive Endocrinology (most recent first):

Academic Appointments (most recent first):

Specialized Training In Assisted Reproductive Technology:

Description of Current Practice:

IV. QUALIFICATIONS OF KEY PERSONNEL
(a current Curriculum Vitae must be attached for each person)

3) **ANDROLOGIST/SEMENOLOGIST**

Name:
Address:
Phone ( )
Sex: Social Security # Citizenship

Date of Birth: Place of Birth:
American Board of Eligible Year Certified Year

Medical/Graduate School

Dates: Degrees:

Internship

Dates: Specialty:

Residency

Dates: Specialty:

Pre-Doctoral Fellowship **Post-Doctoral Fellowship**

Dates: Specialty: Dates: Specialty:

Other Postgraduate Training (6 months or more)

Dates: Specialty:

Clinical Practice (if any) (most recent first):

Academic Appointments (most recent first):

Specialized Training In Assisted Reproductive Technology:

Description of Current Position:

IV. **QUALIFICATIONS OF KEY PERSONNEL** (a current Curriculum Vitae must be attached for each person)

4) **EMBRYOLOGIST**

Name:
Address:
Phone ( )
Sex Social Security #: Citizenship:
Date of Birth: Place of Birth:

Education

Dates: Degree: Dates: Degree:
Dates: Degree: Dates: Degree:
Fellowship Dates: Specialty:
Academic Appointment (most recent first):

Specialized Training In Assisted Reproductive Technology:

Description of Current Position:

SUMMARY OF CENTER'S EXPERIENCE

IN VITRO FERTILIZATION

Starting Date of Program (First Patient Treated) ____________________

Summary of Results through ____________________

	# Cycles Begun	# Attempted Oocytes Recov	# of Embryo Replacements	# Clinical Pregnancies
Up to 1984				
1985				
1986				
1987				
1988				
1989				

*A clinical pregnancy includes hCG secretion with either ultrasound documentation of an intrauterine gestational sac (preferably with fetal heart motion) or pathologic confirmation from an ectopic gestation or spontaneous abortion.

Number of Live Infants Delivered ______ from ______ Mothers

GIFT

	# Patients	# Cycles	# Clinical Pregnancies	# Ectopic Pregnancies	# Delivered Pregnancies
Up to 1984					
1985					
1986					
1987					
1988					
1989					

FROZEN EMBRYO OUTCOMES

	# Patients	# Embryos Frozen	# Embryos Transferred	# Transfer Procedures	# Clinical Pregnancies	# Delivered Pregnancies
1985-1986						
1987						
1988						
1989						

DONOR OOCYTE / EMBRYO OUTCOMES

	# Patients	# Oocyte Cycles	# Embryo Transfer Cycles	# Clinical Pregnancies	# Delivered Pregnancies
1985-1986					
1987					
1988					
1989					

I hereby apply for membership in the Society For Assisted Reproductive Technology on behalf of our Center as well as all qualifying team members. I certify that all of the above statements are correct.

I understand that the requirements of membership include participation in the Registry as well as remaining actively involved in Assisted Reproductive Technology.

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Program Director's Signature

IN VITRO FERTILIZATION (IVF) AND GAMETE INTRAFALLOPIAN TRANSFER (GIFT) IN THE UNITED STATES DURING 1987 AND 1988

PRESENTED BY

MARTIN M. QUIGLEY, M. D., PRESIDENT
SOCIETY FOR ASSISTED REPRODUCTIVE TECHNOLOGY (SART)

Prepared for: THE SUBCOMMITTEE ON REGULATION AND BUSINESS OPPORTUNITIES
SMALL BUSINESS COMMITTEE
U.S. HOUSE OF REPRESENTATIVES
MARCH 9, 1989

Chairman Wyden, Members of the Subcommittee, I am Martin M. Quigley, M. D. and I am serving this year as president of the Society for Assisted Reproductive Technology (SART). I am a certified Reproductive Endocrinologist as well as Obstetrician-Gynecologist. I direct the Section of Reproductive Endocrinology and Infertility (including the in vitro fertilization (IVF) program) of the Department of Gynecology at the Cleveland Clinic Foundation in Cleveland, Ohio. I have been asked to present the results of a questionnaire survey undertaken in the fall of 1988 by your office concerning the practice of IVF and gamete intrafallopian transfer (GIFT) in the United States during 1987 and 1988.

INFERTILITY

Although infertility has been recognized since biblical times, several factors have simultaneously come together to make it a pressing problem in the United States today. First, the development of effective and safe contraception, the Supreme Court Roe v. Wade decision in 1973 (with the subsequent widespread availability of abortion on demand), and the social acceptability of single parent families have all dramatically reduced the number of adoptable infants who would otherwise have allowed infertile couples to have a family.

Second, the change in social roles in modern America, with a larger percentage of women working outside the home and indeed, often choosing a career before marriage or childbearing, has led to an increased age of women having their first child. In my practice, I commonly see patients in their late 30's through their mid 40's who are seeking medical assistance to have their first child. The age at which a woman wishes to become pregnant is important in view of the well-recognized decrease in a woman's fertility with age. That, coupled with the fact that many of the common causes of infertility, such as endometriosis, ovulatory dysfunction and blocked tubes, become increasingly more common as a women gets older make these women more likely to have problems achieving a pregnancy.

Third, analogous to the significant progress in other fields of medicine, diagnosis and treatment of infertility has changed dramatically in the last 20 years. Effective drugs are now available to induce ovulation and treat endometriosis. Microsurgical techniques permit reconstruction of Fallopian tubes damaged by infection. The laparoscope, a diagnostic telescope that permits direct visualization of a woman's internal reproductive organs, has allowed the easier diagnosis of many causes of infertility such as endometriosis and pelvic adhesions. Coupling the laparoscope with the new generation of surgical lasers has allowed treatment of these conditions without the need for major surgery. Sensitive, accurate measurements of a woman's hormone levels in her blood are universally available. High frequency sound waves (ultrasound) permits the safe and painless monitoring of a woman's ovarian cycle.

Thus, the American couple today is more likely to have infertility problems than in the past, is less likely to be able to circumvent their infertility by adoption but fortunately is able to avail themselves of modern medical diagnostic procedures and treatments.

SPECIFIC INFERTILITY ETIOLOGIES AND TREATMENTS

Infertility is a couple problem and it is mandatory that both partners be thoroughly evaluated to maximize the chances of successfully establishing a pregnancy. It has been estimated that 40% of all infertility is due to low sperm numbers or motility in the husband, 40% due to blocked or damaged Fallopian tubes in the wife, 25% due to problems with ovulation, 15% due to endometriosis, 5% due to other factors and a small percentage (typically estimated to be between 2 and 5%) to be unexplainable with our current knowledge. These figures add up to more than 100% as some couples have more than one cause for their infertility.

Low sperm count and motility can often be treated with drugs, surgery, or procedures in which sperm are concentrated and used for insemination of the wife. The use of anonymous donor sperm is available when conventional male treatments are inappropriate or unsuccessful.

Blocked Fallopian tubes can often be opened or reconstructed with microsurgical and laser procedures. Usually ovulation problems are successfully treatable with drugs. Endometriosis can be treated surgically or suppressed with hormones, and a wide range of treatments are available for the other less common infertility causes.

Overall, recognized treatments are available for most infertility causes. Eighty-five percent of infertile couples can be treated with conventional methods. At least half of infertile couples will achieve a successful pregnancy with these treatments.

IN VITRO FERTILIZATION

The birth of Louise Brown in July 1978 capped over a decade of research by the British team of Patrick Steptoe and Robert Edwards. Since the birth of Elizabeth Carr in December 1980 in Norfolk, Virginia, there have been between 3,000 and 5,000 live births resulting from IVF in the United States alone.

As performed today, IVF involves several steps. First, the woman is treated with conventional ovulation inducing drugs in order to produce the simultaneous development of several eggs within the ovaries, instead of the one that usually develops during the woman's menstrual cycle. The development of the multiple eggs is monitored by hormone assays and ultrasound scans. When the ovarian follicles (small fluid-filled cysts in which the eggs are developing) are judged to be mature, the woman is given another hormone injection to induce maturation of the egg itself. Today most egg collection procedures are performed using ultrasound to locate the ovarian follicles and guide recovery of the eggs. The eggs themselves are removed by means of a thin needle inserted through the top of the vagina into the ovary. The recovered eggs are placed in a laboratory incubator for a few hours to allow final maturation and then the husband's sperm is added. About 16 hours later the eggs are examined for signs of fertilization and 24 hours later are re-examined to make sure they are dividing normally. The early pre-embryos are then placed in the wife's uterus by means of a small plastic tube passed through the cervix.

The "classic" patients treated with IVF are those in whom the wife has absent or irreparably blocked Fallopian tubes. In these women the physical barrier to the meeting of the egg and sperm is bypassed by the IVF process. Once IVF had been shown to be successful in these patients, other infertile couples, for whom conventional therapy had been tried unsuccessfully or for whom no therapy was available, became candidates for IVF. Specific examples of these patients include women with endometriosis who had previously undergone surgical treatment and hormonal suppression and couples in whom no explanation for their infertility had been found. Since about 50,000 sperm are all that are usually required to fertilize an egg in the laboratory, rather than the 20 million typically required for normal conception, couples in whom the husband has untreatable reductions in sperm count or motility are also potential candidates for IVF.

In summary, IVF involves removal of the eggs from the wife's ovary, addition of the husband's sperm in the laboratory, documentation of fertilization and early embryonic development, and placement of the pre-embryo in the wife's uterus, typically two days after egg recovery.

Currently IVF is recommended treatment for couples with otherwise untreatable infertility. This includes couples with tubal disease, male factors, endometriosis, and unexplained infertility. It must be emphasized however, that IVF is the treatment of last resort and is not an appropriate choice or recommendation when other infertility treatments are available.

GAMETE INTRAFALLOPIAN TRANSFER

The GIFT procedure achieved its first reported successful pregnancy in 1984. This procedure is, in many ways, analogous to IVF, but has important differences. The principal difference is that with GIFT, instead of allowing fertilization to occur in the laboratory, eggs and sperm are mixed and immediately placed in the wife's Fallopian tube (where fertilization normally occurs). Thus, couples to be treated with GIFT must have at least one normally functioning Fallopian tube in the wife. Similar to IVF, patients are treated with ovulation inducing drugs to develop multiple eggs at the same time and have the development of these eggs monitored by hormone measurements and ultrasound scans. Most GIFT procedures are done with egg collection performed while directly observing the wife's ovaries with the laparoscope. Using the laparoscopic procedure, the egg/sperm mixture is immediately returned to the wife's Fallopian tubes.

The couples to be treated by GIFT include patients with limited endometriosis (normal pelvic anatomy), unexplained infertility, and male factor (as in IVF many fewer sperm are required for GIFT than natural conception).

The advantages of GIFT include a higher pregnancy rate than usually achieved with IVF and the fact that the procedure is more acceptable to certain religious groups. The disadvantages include the fact that general anesthesia and the laparoscope are used for egg recovery and that, unless pregnancy occurs, the couple receives no information as to whether the wife's eggs were fertilized by the husband's sperm. In addition, not all infertile couples are able to be treated with GIFT, ie, the wife must have normally functioning Fallopian tubes.

Similar to IVF, GIFT is only appropriate for couples in whom all conventional infertility treatments have been tried unsuccessfully.

BACKGROUND FOR THE SUBCOMMITTEE'S SURVEY

IVF and GIFT treatments have come under scrutiny for a number of reasons. First, IVF and GIFT are both expensive because of the large number of specially trained personnel required due to the complexity of the monitoring, stimulation and embryo laboratory procedures. Insurance coverage is often unavailable, as many insurance companies decline to provide reimbursement for any diagnostic procedures or treatments relating to infertility. Even companies that usually cover infertility treatments often consider IVF and GIFT to be "experimental", irrespective of the fact that between 3,000 and 5,000 babies have been born in the

United States using these techniques. (Both the American College of Obstetricians and Gynecologists and the American Fertility Societies (AFS) have issued policy statements that IVF is no longer considered experimental.) The end result is that patients are often forced to personally bear a large proportion of the cost of these treatments.

Second, it is not well recognized that human reproduction itself is relatively inefficient. It has been estimated that at best 25-30% of normal couples with no infertility factors will achieve a pregnancy in any given menstrual cycle. Obviously couples requiring infertility treatment are not "reproductively normal" and certainly are unlikely to achieve the same degree of success.

Third, many of the manipulations required for the IVF or GIFT treatment cycle, such as ovulation inducing agents, general anesthesia, the physical acts of aspirating eggs from the ovary and placing embryos in the uterus as well as the psychological stress involved with an exhausting and expensive procedure are likely to further reduce the possibility of successful pregnancy establishment. The IVF treatment process itself is extraordinarily complex and requires the interaction and cooperation of clinicians and laboratory scientists. Even after a decade of experience, we still have not discovered the "ideal" hormone regimen to produce multiple eggs nor has the basic research been able to be undertaken (due in large part to the prohibition against Federal support of such research) to thoroughly recognize the requirements for normal human fertilization and embryonic development. Everyone doing IVF has had the experience that sometimes, for no apparent reason, no patients get pregnant while the next week or the next month, using completely identical procedures, culture media, and equipment, a highly satisfactory pregnancy rate is achieved.

HOW SHOULD DATA BE PRESENTED

There are several major steps in IVF treatment. These include ovarian stimulation, egg recovery, uterine placement of pre-embryos, pregnancy establishment, and finally, birth of a live child.

The fact that human pregnancy is 9 months long necessitates that the final outcome of a treatment cycle may not be known for many months. It must be recognized that, by its design, a survey such as this Subcommittee's, when reporting results for 1987 will, by necessity, be talking about deliveries, most of which have occurred as a result of treatments performed in 1986, and the treatments actually performed in 1987 will often not result in deliveries until 1988.

Most IVF programs report their success rates in terms of clinical pregnancies (the combination of ultrasound demonstration of a gestational sac in the uterus and measurement of the pregnancy hormone, hCG, in the woman's blood) per procedure. Although estimates of normal human pregnancy losses range up to 71%, between 15 and 30% of natural, clinically recognizable human pregnancies end with miscarriage. Reported IVF spontaneous miscarriage rates have typically been around 30%. Although live births are the only meaningful statistic as far as patients are concerned, the lag period from treatment to final outcome necessitates the use of "clinical pregnancy" per procedure rates to present the most current statistics.

Approximately 20 to 25% of all patients beginning an IVF or GIFT stimulation cycle will not have an attempt at egg recovery, usually due to an abnormal response of the women's ovaries to the ovulation inducing drugs. Today almost all patients having an attempted egg recovery will have the recovery of at least one fertilizable egg. Although certain subgroups, such as male factor patients, will have a lower rate of fertilization, in general, between 85 and 90% of women who have eggs recovered will have embryos placed in the uterus.

The choices for the procedure to be used as the denominator for expressing pregnancy rates include: patients beginning stimulation cycles, patients having attempted egg recoveries; and patients having embryos placed in the uterus. As the major discomfort, risk and expense is faced in the egg recovery procedure, the per attempted egg recovery is usually chosen as the denominator. Thus, clinical pregnancies established per attempted egg recovery are the standards used by most IVF programs to report their results.

However, as mentioned above, the only statistic that really matters to patients is the birth of a live child. Therefore, for the purposes of this survey, the data will be presented in terms of live births per attempted egg recovery procedure as much as possible. By necessity, 1988 data will include a combination of live births and continuing pregnancies. As mentioned above, this type of reporting will lead to certain inaccuracies. For example, the live births in 1987 used as the numerator will largely represent 1986 treatments outcomes, while the 1987 treatments used as a denominator will largely result in births in 1988. However, as the reporting is consistent for all programs, meaningful comparisons can be made among programs and patients can make better judgments as to the realistic expectation of pregnancy when undertaking IVF and GIFT treatments.

NATIONAL IVF/ET REGISTRY

In the fall of 1986, a national IVF/ET registry was developed as a joint project of SART, The AFS and Medical Research International. The purpose of this registry is to allow scientific investigation of all aspects relating to IVF and related technologies. In order to maximize the accuracy of submitted data, participants have been guaranteed that the data they submit will be anonymous, ie, no specific identification of results with a particular clinic will be permitted. Participation in the Registry required for members of SART and is also open to all IVF programs.

The Registry publishes annual reports in FERTILITY AND STERILITY, the official journal of the AFS. Already, two reports have been published, the first in February 1988 covering 1985 and 1986, and the most recent, reporting 1987 data, was published in January of this year. Thirty clinics provided data for 1985, 41 for 1986 and 96 for 1987. If we use the same reporting system used by the Subcommittee's survey, the live birth per egg recovery procedure rates calculated from the published Registry data were 8.9% in 1985 and 9.2% in 1986. In 1987, when the final outcome of all cycles was known, 11.4% of the retrieval cycles resulted in a live born child.

Inadequate data to calculate meaningful pregnancy rates for GIFT were reported to the Registry for 1985. In 1986 23.2% of the GIFT cycles resulted in a clinical pregnancy while in 1987, 18.4% of the GIFT retrievals resulted in a live born child.

CHAIRMAN WYDEN'S SURVEY

At a June, 1988, hearing of this same Subcommittee, Chairman Wyden announced plans to conduct a survey of all clinics in the United States conducting IVF and/or GIFT treatments in 1987 and 1988. Working together with past and present officers of the AFS and SART, a four-page questionnaire was distributed to all identifiable IVF and GIFT clinics. As of the present time (March 7, 1989), the data from 139 clinics has been correlated. As a general statement, virtually all reporting clinics conducted IVF cycles with about 85% also conducting GIFT cycles. With a few exceptions, most reporting clinics performed many more IVF cycles than GIFT cycles.

IN VITRO FERTILIZATION

In 1987, 11,588 IVF stimulation cycles were initiated. In 24.2%

of these initiated cycles no attempt at egg recovery was made. 8,782 attempts at egg recovery were made, of which 87.4% culminated in an embryo transfer procedure. There were 1019 live born children in 1987 resulting from IVF, a rate of 11.6% per egg recovery procedure or 13.3% per embryo transfer procedure.

In 1988, there were 13,840 reported stimulation cycles. In 20.3% no attempt at egg recovery was made. 11,032 egg recovery procedures were performed of which 87.5% resulted in embryo transfer. 577 live born children resulted and 1148 clinical pregnancies were listed as ongoing at the time of completion of the questionnaires. Together, there were 1725 reported live births or continuing pregnancies, which is a rate of 15.6% per egg recovery procedure or 17.9% per embryo transfer procedure. (See Table I).

__GIFT RESULTS__

In 1987 there were 3,347 GIFT stimulation cycles, of which 26.5% were terminated without an attempt at egg recovery. 2,461 egg recovery procedures were performed which resulted in 351 live born children, a rate of 13.3% live births per egg recovery procedure. In 1988, 3,937 stimulation cycles were begun of which 20.3% did not result in attempted egg recovery. 2,976 egg recovery procedures were performed resulting in 342 live born children and 513 continuing pregnancies. The live births plus continuing pregnancies represent 28.7% of the egg recovery cycles. (See Table II.)

SPECIFIC CENTER RESULTS

One of the criteria for membership in SART is the performance of at least 40 stimulation cycles per year. We felt that, under normal circumstances, this was the minimum number of cycles per year that would allow a clinic to maintain the necessary expertise, especially in the embryo laboratory. When the 1987 IVF data from the Subcommittee's survey are examined, there were 72 clinics that initiated at least 40 stimulation cycles. 70 of these clinics (97.2%) reported at least one live birth in 1987. Of the 70 clinics with live births, the minimum live birth per egg collection procedure rate was 1.5% and the maximum rate was 25.3%. Three clinics reported rates over 20% and 16 reported rates over 15%. Conversely, 9 programs had rates less than 5% and 20 had rates less than 8% (excluding the 2 clinics with no live births). The remaining 34 clinics had rates between 8 and 15%. (See Figure 1.) When the differences in patient populations are taken into account, I believe these data show a reasonable amount of clinic to clinic consistency.

CAUTIONS ABOUT THE DATA

The questionnaires were distributed in November of 1988. Some questionnaires were returned immediately, others were received up through last week. Thus, some questionnaires will contain complete cycle data for 1988 while others only include partial year data for 1988.

The true live birth rate per egg collection attempt during 1987 is likely to be higher than actually calculated. As there were more reported egg collection cycles in 1988 than in 1987, it is virtually certain that there were fewer cycles performed in 1986 compared to 1987. Many of the 1987 children resulted from 1986 treatments. Thus, dividing the number of children born in 1987 by the number of 1987 egg collection attempts will falsely lower the true rate of live births. Similarly, the 1988 data has two inherent inaccuracies. First, similar to 1987, the increase in numbers of treatments and the lag period from treatment to delivery will result in an underestimation of the actual live birth rate. However, because insufficient time has elapsed for the outcome of all pregnancies to be known, a proportion of the pregnancies listed as continuing (perhaps 30%) will end in miscarriage or ectopic pregnancy and thus, not result in a live born child. Whether these two factors together will lead to an overall overestimate or underestimate of the actual live birth rate per aspiration cycle cannot be determined from the available data.

SUMMARY

For several reasons, infertility and its treatment have become more important in recent years. Advances in infertility practice have led to the development of treatments for most of the causes of infertility. For the fraction of infertile couples for whom infertility treatment has been unsuccessful or for whom there is no other therapy, IVF and GIFT are available.

Overall, IVF and GIFT are becoming more widely applied technologies in the United States. Several factors, principally the increase in numbers of treatment cycles performed each year, the unpredictable outcome of pregnancies in progress and the inability to directly connect live births and treatment cycles with this data collection technique leads to uncontrollable inaccuracies in the calculation of live birth rates. Using the previously published data from the IVF Registry as well as the Subcommittee's survey data, there has been a progressive increase in the live born per egg collection procedure rate from 8.9% in 1985 to 9.2% in 1986 to 11.6% in 1987 to 12.5% in 1988 (making the assumption that 70% of pregnancies reported as continuing in 1988 will result in a live born child). As a general statement, the likelihood of a live born child per egg recovery procedure is greater with GIFT than IVF, although not all patients treatable by IVF are treatable by GIFT. Specifically, the 1988 data suggests that the GIFT live born rate for treatment is about double that achieved with IVF.

Chairman Wyden, Subcommittee members, I thank you for your attention and I would be glad to respond to any questions you may have.

Table I. SUMMARY OF IVF RESULTS

	1987	1988
Stimulation Cycles	11,588	13,840
Egg Recovery Procedures	8,782	11,032
Embryo Transfers	7,672	9,658
Live Births	1,019	577
Continuing Pregnancies	-	1,148

Percentages

	1987	1988
Scratched Cycles	24.2%	20.3%
Embryo Transfer (per aspiration)	87.4%	87.5%
Live Birth (per recovery procedure)	11.6%	-
Live Birth plus Continuing (per recovery procedure)	-	15.6%
Live Birth (per embryo transfer)	13.3%	-
Live Birth plus Continuing (per embryo transfer)	-	17.9%

This includes data from the 138 clinics performing IVF which were available for analysis on March 7, 1989.

Table II. SUMMARY OF GIFT RESULTS

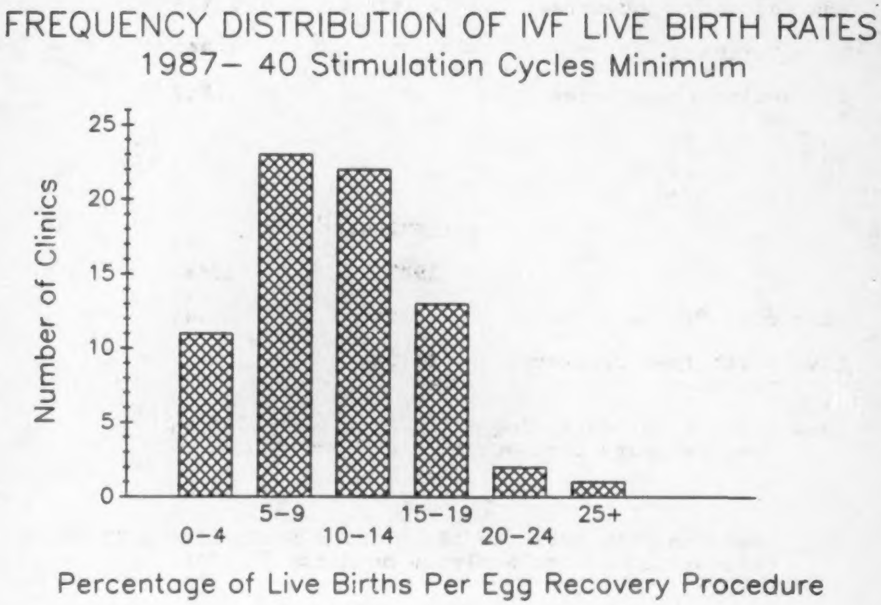
	1987	1988
Stimulation Cycles	3,347	3,937
Egg Recovery Procedures	2,461	2,976
Live Births	351	342
Continuing Pregnancies	-	513

Percentages

	1987	1988
Scratched Cycles	26.5%	24.4%
Live Birth (per recovery procedure)	14.3%	-
Live Birth plus Continuing (per recovery procedure)	-	28.7%

This includes data from the 121 clinics performing GIFT which were available for analysis on March 7, 1989.

Figure 1.


FREQUENCY DISTRIBUTION OF IVF LIVE BIRTH RATES
1987– 40 Stimulation Cycles Minimum
Number of Clinics
25
20
15
10
5
0
0–4
5–9
10–14
15–19
20–24
25+
Percentage of Live Births Per Egg Recovery Procedure

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TESTIMONY FOR:
THE SUBCOMMITEE ON REGULATION AND BUSINESS OPPORTUNITIES

PRESENTED BY

DR. ALAN H. DECHERNEY

MARCH 9, 1989

I would like to address the topic of exploitation and disillusionment in regard to physicians who practice infertility medicine. There has been a tremendous growth in the number of doctors practicing infertility medicine in the past few years. This is due to a number of reasons, including increased patient need and demand, the malpractice crisis, the development of new commercial technology and the entrance of for-profit organizations into the field in greater number.

The malpractice crisis has had a tremendous impact on the practice of Obstetrics and Gynecology. Obstetrics has become an area of threat to the physician and therefore they have changed to "**safer**" means of practice. The practice of infertility medicine represents an excellent example. If we look at outcome in general, infertility overall has a cure rate of approximately 60%; therefore it is extremely difficult to monitor an individual doctors success rate since the failure rate is so high (ie. 40%)-plus, this is also dependent upon the etiology of the infertility. In vitro fertilization has a lower success rate than reversal of tubal ligation, as an example.

The development of new technologies has, in the past ten years, caused a tremendous change. As we are now able to do many things that we were not able to do in the past, so doctors now have the opportunity to manipulate the biologic system in a number of ways. Some of these are obviously beneficial for patients and some can be detrimental.

The entrance of for-profit organizations into medicine and the convenience of medicine, at least philosophically, into a "**business**" have caused new priorities in the practice of medicine. Certainly fiscal responsibility is important but it also opens doors for economic exploitation. Exploitation is defined as an "unjust or improper use of another person for one's own profit or advantage". If substandard or unnecessary medical care is rendered to the infertile couple, exploitation has occurred. How can exploitation occur?

One example of exploitation is inappropriate use of credentials. Taking a two day course in IVF and calling yourself an IVF expert is an example of this misuse of the new reproductive technologies, such as promising things that can't be accomplished. Truth in advertising is an area with potential for exploitation and in fact is the essence of this hearing today.

Infertility patients are exceptionally vulnerable. The practice of infertility is safe; no one dies. As mentioned, success rates are not high; therefore failure rates are difficult to assess. Most importantly, these patients are desperate to have children and will go to any length to accomplish this goal.

There are a number of built-in mechanisms to protect patients. One is the credentialing process. The American Board of OB/GYN provides superior credentialing. Physicians take written and oral exams to attest to their competence in Obstetrics and Gynecology and Reproductive Endocrinology. The American Fertility Society, through S.A.R.T and other affiliated societies, provides surveillance and sets practice and ethical standards. The question that arises is, "is outside monitoring important and necessary?"

Certainly I endorse the regulation of laboratories. There is a well-set-up, state-by-state mechanism for this and our IVF and gamete laboratories should come under the same scrutiny. The larger question then is, "should some form of regulation of clinical practice occur?", ie., determining what credentials people need to practice infertility medicine, monitoring success and failure rates, and establishing ethical and quality assurance issues. The British have set up a voluntary licensing authority made up of physicians and other members of society who inspect and scrutinize centers that perform the new reproductive technologies. This is highly successful and perhaps can provide a model for us.

In 1987 only 28 out of 98 (30%) centers had no success and only 3 of those centers did more than 30 cycles. In 1988 only 12 out of 119 (10%) had zero success and only 5 of these did more than 10 cycles and all did less than 22 cycles that year.

In regard to the data collected by the Wyden Committee, the most important aspect of this, other than the data itself, is the ability for the individual centers to qualify and explain their data. Although this report has the potential for much good it also has the potential for some harm in that centers that select their patients to be successful will, on paper, look better than other groups. The center that does women over the age of 40 or includes males with a low sperm count or will do more than two cycles in patients will definitely have lower success rates and we would hate to disenfranchise these patients from care. In summary, some exploitation of patients by physicians in the field of infertility does exist. The magnitude of this is not known and my estimate is that the proportion is quite small. The dissemination of data is helpful but also has the potential for harm and physicians must have the ability to qualify their data. Lastly, I support the IVF Registry as it exists under the aegis of the American Fertility Society, S.A.R.T and Medical Research International. This provides a valuable tool for patients and physicians alike to evaluate success rates.

I would hope that this collection and dissemination of data will lead to improved doctor/patient relationships and not favor what is already, in some instances, an adversarial one.

REGULATION OF THE ADVANCED REPRODUCTIVE TECHNOLOGIES

TESTIMONY FOR

UNITED STATES CONGRESSIONAL SUB COMMITTEE

ON

REGULATION AND BUSINESS OPPORTUNITIES
B-363 RAYBURN HOUSE OFFICE BLDG.
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MARCH 9, 1989

BY

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Congressman Wyden, members of the committee for Regulation and Business Opportunities, I would like to thank you for inviting me to speak to you concerning the issues involved in providing patient care in the area of the assisted ~~high tech~~ reproductive technologies. ~~medicine~~. I would also ~~first~~ like to thank you and your staff for continuing to work to increase public awareness and improve patient knowledge as to the possible pitfalls with the new reproductive technologies or with the providers of those services. Almost a year ago, in this room, we heard the terrible plight of a couple abused by the very medical system that should have protected and helped them to achieve their goal of having a child. Since that hearing, many such stories, which depict the desperate nature of the infertile couple, have surfaced. It is not my purpose today to discuss how the system has failed; instead, I would like to offer some discussion to change that system so that it may provide the patient with emotional and financial support.

The hotly debated issue of outcome reporting is still a concern to me, and, I think, to the patient population we serve. The questionnaires received by Your ~~this~~ committee reflect the outcome statistics reported on an individual center basis. One hundred twenty-one (121) centers provided information. In 1987, 27 of these centers reported no pregnancies in 357 egg recoveries for in vitro fertilization. These centers constituted 22% of centers reporting and accounted for 2.5% of cycles performed with a net cost to the patients of approximately 1.8 million dollars. Of the centers that did not respond to your request, what percentage of cycles do they represent, and how many patient dollars were spent in centers that have yet to achieve a pregnancy?

Even though I feel that this report of 121 identified clinics is important, how reliable is it? Is the anonymous IVF registry report a more honest representation of outcome? I do not know. However, I think for any of this data to be acceptable, an independent auditing would be required.

Of equal concern is the obvious absence ~~of several large,~~ all centers including some well recognized centers which have not made their data a part of this report. Are these individuals implying by their refusal, that they can play by a different set of rules? Do some centers feel immune to the review process or standardization of policy in these areas? If so, a dangerous precedent is being established by accepting this silence.

The information that has been available to the consumer (patient) prior to this report has been scarce and often misleading. This is not surprising when a review of the medical literature in this field is undertaken. I recently had cause to review the last several years of scientific publication in the areas of in vitro fertilization and found to my surprise that even with my level of sophistication, it was difficult to extrapolate live birth outcomes from a large percentage of these reports. If this type of information is being accepted by peer review scientific journals, how can we expect the patient to receive clear, concise data upon which she can base a decision concerning her treatment options? The honest discussion of factual outcome data will go a long way in decreasing emotional

I feel very strongly that idenification of Live births produced per procedure performed is the only markers that the patients will utilize in their decision making.

stress in this very vulnerable population of patients.

Another area of concern and stress to this patient group is the increasing financial burden they incur for an attempt to have a child . Whether you look at the cost of basic testing and evaluation, or that of the assisted reproductive technologies, the cost to the patient is escalating rapidly. Along with the fact that in most states infertility evaluation and treatment is a non-covered item by health insurance, the infertile couple bears the entire expense. With escalating drug and hospital costs, the ability to have a child, if infertile, is rapidly becoming available only to couples with financial means.

After your hearing in June of 1988, much progress towards improving the quality of care and the assurance of that quality has occurred. I strongly feel, however, that voluntary reporting or unaudited reporting accomplishes only part of the goal. It appears from our efforts through SART (Society for Assisted Reproductive Technology), the American Fertility Society and other national organizations, that we have limited, if any, ability to regulate or standardize the quality of care in this area. I strongly feel, therefore, that there needs to be a multi-disciplined approach to improve consumer protection. With your permission, I would like to suggest the following model:

1) The laboratories performing tests or evaluation of oocyte and sperm function should be licensed like any other diagnostic laboratory on a state to state basis.
2) Laboratories performing Gamete Intrafallopian Transfer (GIFT), Zygote Intrafallopian Transfer (ZIFT), Tubal

Embryo Transfer (TET), In Vitro Fertilization (IVF), embryo freezing and other assisted technologies should be licensed on a state to state basis or fall under national guidelines. Organizations that might offer oversight in this process would be the College of American Pathologists (CAP), American Association of Tissue Banks (AATB) and others. These organizations would work in conjunction with an independent board of expert consultants to establish guidelines and standards for these procedures.

3) A national effort should be undertaken to mandate coverage of infertility evaluation and treatment by third party payers. The cost would be born by the individual insured in the form of premium riders for those seeking coverage. The insurance carriers, in turn, can request certification of facilities ~~and center~~ to determine levels of reimbursement, thus improving the level of quality assurance to the patient population.

4) The final area of oversight should come from an independent licensing board (ILB). The purpose of this board would be to site visit and review clinical, laboratory, physical facilities, personal and patient reporting on a year to year basis. This independent board would be made up of clinicians, scientists, statisticians and ethicists. The ILB would, at the request of a center, evaluate and certify the facility

for a definitive period of time. The expense of this review and certification would be born by the center. The list of accredited centers would be published with an annual report for public perusal. The formation of a group such as the ILB will give the patient a level of security when entering a certified center, and it would also give third party payers accurate information for reimbursement purposes. Centers that do not qualify for certification may associate formally with a certified center in order to meet personal requirements, etc. In this way, potential overlap, which increases cost, may be reduced and a network, or regionalization, of this highly technical area of medicine may come about.

I do not know whether these approaches are possible or feasible on a state or national level. However, these are the issues that we must discuss. The patients we care for are extremely vulnerable and susceptible to unscrupulous practices. Even though that occurs in a very small percentage of cases, the system should be designed to exclude even the slightest possibility of emotional and/or financial manipulation. We all must maintain the ability as physicians to treat our patients to the best of our abilities, but we also must be able to withstand peer or government review as any other professional.

Again, I thank you for your energy and interest in these very sensitive issues in human reproductive health care.

TESTIMONY OF GARY B. ELLIS

OFFICE OF TECHNOLOGY ASSESSMENT
U.S. CONGRESS

BEFORE THE
SUBCOMMITTEE ON REGULATION AND BUSINESS OPPORTUNITIES
HOUSE COMMITTEE ON SMALL BUSINESS

March 9, 1988

TRENDS IN MEDICALLY ASSISTED CONCEPTION

Thank you, Mr. Chairman. I am Gary Ellis, a Senior Analyst at the Office of Technology Assessment (OTA). Last year, OTA reported on the medical, scientific, legal, economic, and ethical issues surrounding infertility and medically assisted conception. Two reports were published: One, called *Infertility: Medical and Social Choices*, and a second, *Artificial Insemination*, which is a survey of the practice of artificial insemination in the United States. My testimony this morning focuses on developments OTA has observed in the wake of those reports.

At the outset, permit me to make a summary statement about in vitro fertilization (IVF) and its allied procedure, gamete intrafallopian transfer, or GIFT. These medical procedures, which did not exist in the United States just 10 years ago, offer hope to infertile couples who may have lost hope, and moreover are delivering babies to couples who may have been unable to conceive without assistance. About these simple and positive facts, there can be no dispute, and I emphasize them. The babies, the children, are there. One clinic in Norfolk VA in January delivered its 500th baby conceived by in vitro fertilization.

The looming question is: At what cost — both financial cost and emotional cost — does this hope and these babies come, not only to the couples who are successful, but also to couples who are unsuccessful, and society as a whole?

Since OTA delivered its report, Mr. Chairman, that question has been actively examined by your Subcommittee, by the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Operations, in professional journals, and in the print and broadcast media. The answer to the question — At what cost...? — is complex, indeed.

First, some perspective. This year, there will be about 3.8 million babies born in the United States. As many as 5 percent of the total will be conceived with medical assistance. Americans spend about $1 billion a year on medical care to combat infertility. As many as half of the infertile couples seeking treatment are ultimately unsuccessful, despite trying various avenues of treatment. And, that places infertility treatment well within the broad spectrum of success rates for various high-tech, and low-tech, medical procedures.

OTA estimates that in 1987 Americans spent about $70 million on some 14,000 to 21,000 attempts at in vitro fertilization. Some of that was paid by insurance companies and the balance by patients; insurance coverage for IVF is highly variable. Despite these statistics and its notoriety, IVF is a relatively rare procedure in infertility treatment. OTA estimates that less than 5 percent — perhaps, less than 1 percent — of couples obtaining infertility treatment undertake either in vitro fertilization or GIFT, at present.

On average, 9 out of 10 attempts at IVF end in failure. Put another way, the percentage chance of delivering a baby after one IVF stimulation cycle is in the single digits. In 1986, on average, couples had a 6 percent chance of taking home a baby after one IVF stimulation cycle, according to data collected by Medical Research International and the American Fertility Society. In January, these same authors published more recent data, for 1987, but it is not possible to determine an IVF take-home baby rate for 1987 from their report. The Subcommittee's survey of some 140 IVF/GIFT clinics, presented today, indicates that the IVF take-home baby rate for 1987 was about 9 percent per IVF stimulation cycle.

It is important to note that human reproduction in its *unassisted* form is remarkably inefficient. Substantial embryonic loss is a routine part of the life cycle among humans and all mammals. Most eggs are never fertilized, and if fertilization occurs, as many as one-fourth to one-third of human conceptions end in miscarriage, for reasons that are poorly understood. The seemingly low success rates for in vitro fertilization must be thought of in the context of what happens in nature.

Much emphasis has been placed on success rates by both practitioners and patients. Some IVF clinics incorporate statistics about their success into their advertising, and I have brought along some examples. OTA does not formally monitor the advertising of IVF clinics and has conducted no systematic evaluation. These examples were obtained on an ad hoc basis, in some instances from interested citizens who mailed them in to OTA.

The advertisements describe clinics as having the highest success rate in a geographic area; list success rates in percentage form without giving the numerator and denominator of the rate; list numbers of babies born at a group of clinics without disclosing how many were born at specific clinics in the group; and so forth. Advertisements such as these are less than forthright in the ways in which they present information. That is both troubling and inappropriate in a field in which forthrightness is absolutely necessary. The odds do not favor a successful pregnancy for couples undertaking IVF, and complete and realistic disclosure is a must.

In that vein, it is remarkable to find in a patient education booklet distributed for placement in physicians' offices the following:

> "Test-tube baby" or in vitro fertilization programs have a ten to 25 percent success rate per attempt.

No. They have a zero to 25 success rate per attempt. The patient information booklet was published in 1988 by the American Fertility Society.

In the area of consumer protection, Congress could direct the Federal Trade Commission to exercise its authority under section 5(a)(6) of the Federal Trade Commission Act to examine whether advertisement of success rates at various IVF or gamete intrafallopian transfer clinics is misleading, and, if so, to issue appropriate regulations. Regulations could be issued, for example, to standardize the ways in which success rates are reported, so that individuals are better able to make an informed choice about whether and where to undergo a procedure.

The most useful annual reporting by IVF clinics would include, at a minimum:

- number of patients stimulated;
- number of stimulation cycles;
- number of embryo transfer cycles;
- number of clinical pregnancies;
- number of pregnancies delivered; and
- number of multiple pregnancies delivered.

A similar report by practitioners of gamete intrafallopian transfer would also be useful to a number of infertile couples.

These statistics could be subdivided by age ranges of the women undergoing treatment. Age is probably the most relevant predictor of successful treatment. Also, these statistics could be subdivided by primary diagnosis of the infertile couple. Diagnoses would include, at a minimum: anovulation, endometriosis, tubal factor, male factor, and idiopathic. Primary diagnosis is probably second in importance to age as a predictor of success. The resulting two- or three-way matrix of statistics would provide infertile couples with information about how many couples with the female in a particular age range and/or primary diagnosis had been successfully treated by the clinic.

Why would the Federal Government take steps to ensure that infertile individuals are made aware of the efficacy of the treatments offered and of the success record of medical personnel with whom they are consulting? In the case of IVF, there are several reasons:

- Aspects of the technique are still to some extent in a research phase.
- Success rates vary considerably and even at their best are low.
- The procedure is carried out at times in free-standing clinics or other settings that are not subject to all the usual hospital peer-review practices.
- Relevant professional societies do not yet have accreditation programs directed specifically at IVF.
- As the procedure can entail months of drug treatment and repeated surgeries, it can represent a serious health risk and constitutes a major disruption of personal and professional activities.
- IVF is often excluded from insurance coverage, and so may be very costly to individuals.
- The patient population for these services is particularly vulnerable because it largely consists of individuals who have tried for many years to have a much desired pregnancy.

Until the release of the Subcommittee's survey today, success rates of individual IVF clinics were not publicly reported in a standardized manner. This has made it extremely difficult for infertile couples to be fully informed consumers. In fact, it has created in this area of medicine a situation where the doctor/patient relationship is fast becoming a vendor/consumer relationship. The ethic in a vendor/consumer relationship can be one of *caveat emptor*, or "Let the buyer beware." This sets up physicians and patients as adversaries, and is inappropriate. Physicians are more properly advocates for their patients. The efforts of the Subcommittee in publishing clinic-specific data are an important step, Mr. Chairman, toward reversing an inappropriate trend in this area of infertility treatment.

Beyond the issue of reporting by individual IVF clinics lies the fundamental question of substantially improving success rates. In this regard, the ultimate consumer protection is research. Government sponsorship is desperately needed for research protocols that could advance basic scientific understanding of human reproduction and improve the prospects of success for infertile couples.

In July 1988, the Department of Health and Human Services announced plans to revive its Ethics Advisory Board, a body that ceased to exist in 1980. The Ethics Advisory Board is required to advise the Department of Health and Human Services on the ethical acceptability of the conduct and funding of certain proposals for research involving human subjects. A proposed charter for the Board was published in the Federal Register last September 12, and about 175 comments were received from the public. To date, the Department of Health and Human Services has not delivered on its pledge to publish a final charter and revive the Ethics Advisory Board. In the absence of the Ethics Advisory Board, research funding has been blocked.

With ethical issues playing an increasingly prominent role in biomedical and behavioral research, it is appropriate that certain research proposals be reviewed not solely for scientific merit, but for ethical acceptability as well. Few will dispute that respect for societal values is requisite to accepting public funds for research. The proposed Ethics Advisory Board is scheduled to be the chief interpreter within the Department of Health and Human Services of the ethical acceptability of biomedical and behavioral research as the nation enters the 1990s. Research with human subjects falling under the Board's purview may include that with healthy human subjects, as well as demented patients, children, prisoners, AIDS patients, fetuses, and human sperm and eggs.

In the case of human sperm and eggs, the prolonged absence of an Ethics Advisory Board has essentially halted research in human in vitro fertilization. Such a Board is required by Federal regulation to advise the Department of Health and Human Services as to the ethical acceptability of such research before it can be funded. With no Board, no grants can be funded. Investigators do not submit proposals involving human IVF because of a widespread awareness of the de facto ban on such research. The dimensions of this chilling effect of the moratorium on IVF research are such that the National Institutes of Health estimated to OTA that it might receive more than 100 grant applications related to human IVF if the Ethics Advisory Board existed.

Some funds for IVF research have come from pharmaceutical companies, institutional and departmental funds, and patient fees, but any Federal component is missing. The nine-year absence of an Ethics Advisory Board has thus robbed infertile couples seeking IVF of the ultimate consumer protection — as I said before — research.

Mr. Chairman, that concludes my testimony. Thank you for the opportunity to present OTA's analysis of trends in medically assisted conception. I am pleased to answer any questions.

MONITORING ASSISTED REPRODUCTIVE TECHNOLOGY: THE U.S. IVF/ET REGISTRY

TESTIMONY FOR THE

SUBCOMMITTEE ON REGULATION AND BUSINESS OPPORTUNITIES
HOUSE COMMITTEE ON SMALL BUSINESS

PRESENTED BY

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9 MARCH 1989

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MONITORING ASSISTED REPRODUCTIVE TECHNOLOGY: THE U.S. IVF/ET REGISTRY

Mr. Chairman, members of the Subcommittee, my name is Stuart C. Hartz. I am President of Medical Research International, Inc. (MRI), a health research consulting company located in Burlington, Massachusetts. MRI specializes in the design and conduct of clinical trials and epidemiologic studies on the effects of health care products and procedures. I also hold Associate Professorship appointments at Tufts University School of Medicine (Community Health) and at Boston University School of Public Health (Epidemiology and Biostatistics).

On behalf of MRI, and the 155 U.S. member clinics, I appreciate the opportunity to offer my perspectives on the IVF/ET Registry (henceforth referred to as the Registry). Today, I will focus on three major phases of the Registry's activities: its goals, its design and organization, its progress and performance to date, and its possible future directions.

The Registry is a collaborative effort of the American Fertility Society (AFS), the Society for Assisted Reproductive Technology (SART), and MRI. All Registry operations are performed by MRI at its central offices.

Since its inception, the Registry has been financially supported exclusively by Serono Laboratories, Inc. In June 1988, MRI was awarded a contract by the National Institute of Child Health and Human Development (NICHD) to study the potential adverse health effects on women undergoing assisted reproductive technology treatment. The NICHD funding complements that of Serono and is specifically targeted at enrolling 13,000 women at nine clinics in the U.S., whereas the Registry seeks to monitor all patients (and clinics) in the U.S. using the assisted reproductive technologies.

The Registry was established to explore the epidemiology of the assisted reproductive technologies. The Registry's major objectives include: 1) describing the patterns and nature of the assisted reproductive technologies, 2) measuring the relative efficacy of the various procedures with respect to clinical pregnancy initiation and outcome, 3) determining the impact of new or modified technical advances emanating from progressive research, and 4) detecting potential adverse events associated with the assisted reproductive technologies.

More specifically, the Registry seeks to perform epidemiologic research that can serve the interests of infertility physicians and related specialists, national health research institutions, and other public health organizations. A critical role of the Registry is to disseminate the results of its statistical analyses through publications and presentations in the medical literature and at professional meetings. In this way, each clinic can compare its practices to a national "average" profile.

In addition, the Registry acts as the central information source for the media seeking national statistics. By placing its findings in the public domain, through both the medical and lay media, the Registry seeks to make its findings available to patients. In this regard, the Registry has established standard definitions to help insure uniformity of specific terms and statistics. In the broader context of health education, MRI staff participates in community and patient seminars to present and discuss the Registry's published information. We also seek to utilize these community resources; for example, RESOLVE (national) is working with us on our NICHD study by offering patients a gift membership as an incentive for volunteering as a study subject.

Planning and organization of the Registry began in 1985 when Serono requested that MRI join with it and the AFS to design and conduct a national study of assisted reproductive technology practice and outcomes. At the time physicians within the framework of the AFS were organizing the Society for Assisted Reproductive Technology (SART, then the IVF Special Interest Group). A goal of this new society was to develop an on-going registry that would enroll its member clinics. Indeed, SART's charter specifies that, to be a member in good standing, the clinic must submit its data to the Registry annually.
Presently, the Registry seeks to enroll all U.S. clinics (SART

and non-SART) using the assisted reproductive technologies.

An acknowledgement of the Registry's perceived importance within the AFS is that Fertility & Sterility (F&S), the official journal of the AFS, publishes the Registry's summary report each year (the 1985/1986 and 1987 reports are enclosed in the accompanying Appendix). Clinics providing data to the Registry are acknowledged in the annual publication.

The goals and methods for the Registry were first presented to IVF practitioners along with the initial plans to organize SART at the 1985 Annual Meeting of the AFS in Chicago. At this meeting we emphasized that the data submitted by each clinic would remain confidential and would be published as pooled (anonymous) statistics. No one outside of MRI's Registry staff has access to clinic-specific information. The computerized database does not contain clinic or patient names, and clinic identifiers are encoded using a special dictionary. Access to unpublished summary data and results is limited. Most recently, a SART Registry Committee was formed to help MRI review research proposals to utilize the members' data.

During 1986, MRI developed and field tested the two current methods for collecting and processing the data to be collected. Two different methods were chosen to help optimize clinic participation and cooperation since many clinics were unprepared to automate data collection and submission. Thus, clinics forward their data using either (1) a pc-based software system, designed by MRI specifically for IVF/ET clinics, or 2) a set of paper forms summarizing each clinic's treatment and outcome results.

MRI's medical record keeping software is distributed for only a small service fee as an added incentive for its use. The software is continually enhanced to reflect the evolving practice of assisted reproductive technology. In addition, MRI provides ad hoc data collection and computer counseling services related to the Registry to the clinics at no charge. For example, we developed a computer program to help clinics retrieve summary statistics requested by this committee in its recent survey.

The data forms provide the Registry with a clinic's overall summary results (pooling all patients). Among the information collected, for each of the assisted reproductive technologies, are: annual total numbers of patients, cycles, retrieval procedures, oocytes retrieved, transfer procedures, pregnancies, and pregnancy outcomes, including congenital anomalies and chromosomal abnormalities.

Unlike the data forms, MRI's software system allows clinics to record patient- and cycle-specific information, including: patient vital statistics, reproductive history of patient and spouse/donor, medical and drug history, laboratory results, ovulation induction protocols, retrieval, fertilization and transfer procedures and results, pregnancy monitoring and outcome, congenital anomalies, and chromosomal abnormalities, and any adverse drug events.

The Registry reports its findings on a calendar year basis, and asks clinics to begin submitting each (previous) year's data in the beginning of the next year. Follow-up to determine outcome of continuing clinical pregnancies continues until October at which time an article is prepared and submitted to F&S for publication in the next available issue (usually early in the following year).

On enrollment into the Registry, a clinic is required to submit retrospective data on prior years' experiences via the data forms, and to begin prospective data processing using MRI's software package.

The Registry officially began its operations in January, 1987. By the fall of 1987, when (retrospective) data collection ceased, a total of 88 (of the estimated 169) U.S. and 18 foreign clinics had enrolled.

The Registry's first annual statistical report, based exclusively on paper forms, appeared in F&S in February, 1988. It summarized the data submitted by 41 clinics performing assisted reproductive procedures in 1985 and 1986.

The F&S article is enclosed in the accompanying Appendix, and here I will only briefly summarize the key results. For 1986, the 41 clinics reported performing a total of 4867 IVF cycles (attempts) on 3055 different patients (an increase of roughly 24% over 1985). There were 2389 and 2864 IVF cycles with embryos transferred resulting in approximately 14% and 17% clinical pregnancies in 1985 and 1986, respectively. The clinics reported a total of 257 liveborn in 1985, and 311 liveborn in 1986. A major difficulty arises in computing a "livebirth" rate for these years, since clinics did not distinguish between the calendar year of transfer and the calendar year of delivery.

In 1985, only 8 clinics reported performing GIFT versus 25 (of the 41) clinics in 1986. The corresponding numbers of GIFT patients increased sharply from 47 (with 56 GIFT cycles) in 1985 to 419 (with 466 GIFT cycles) in 1986. In 1985 and 1986, the proportion of GIFT procedures resulting in a clinical pregnancy was approximately 5% and 23%, respectively. There were 3 and 64 livebirths reported for GIFT in 1985 and 1986, respectively.

In addition, results for frozen embryo transfers and IVF of donated oocytes were presented for these years. However, due to their relatively low prevalence during 1985 and 1986, I will not describe those results in this presentation.

I would like to offer some observations on the Registry's first report. It was based on a relatively small number of clinics, and thus the results had limited generalizability to all U.S. infertility clinics employing the assisted reproductive technologies. In addition, the data were retrospective, and were exclusively based on the paper form that characterized each clinic, rather on MRI's software that characterized each patient. Thus, only limited data were available for this report.

This first year (1987) was very much a learning year - for SART, MRI and the clinics themselves. Many clinics had never participated in a data collection effort using standardized procedures and definitions, or had to meet prescribed deadlines for data submission. Also, each clinic had to identify and contribute its personnel to the effort. Although clinics had MRI's customized software package to help them, the "start-up" time invested in learning the system was sometimes high especially for clinics inexperienced with computers.

During 1988, the Registry's operations increased greatly. By the end of data collection last fall, we could report a total enrollment of 119 U.S. clinics in 38 states - 96 of which were prepared to submit 1987 data for analysis and publication. These results were recently published in the January issue of F&S.

This report represents a much more accurate picture of assisted reproductive technology practice and outcomes in the U.S. In contrast to the first report, results are restricted to the (1987) calendar year - for both treatment procedures and for pregnancy outcomes. Also, the number of patients and treatment cycles reported by the clinics increased sharply, and approximately 19% of the patient-cycles were summarized via the Registry's software package. In addition, due to our intensive follow-up efforts, less than 1% (17) of the 1976 clinical pregnancy outcomes remained unknown at publication.

The report presents the results for IVF/ET, GIFT, IVF/ET and GIFT in combination, frozen embryo transfers, and IVF/ET with donated oocytes. The article is rather extensive, and as above I would like to only briefly summarize some of the key observations.

During 1987, the 96 clinics enrolled 10,397 patients and initiated 14,647 IVF/ET stimulation cycles of which 74% resulted in oocyte retrievals. For IVF/ET alone, 87% of the retrieval cycles resulted in an embryo transfer cycle.

There were 490 frozen embryo and 60 donor oocyte transfers.

Ninety percent of the clinics had at least one delivery, and overall, a total of 1858 babies were born (1260 from IVF/ET, 489 from GIFT, and the remainder from the other assisted reproductive technologies). The overall delivery rates were 11% for IVF (based on 8725 retrievals), 18% for GIFT (based on 1968 GIFT retrievals), 20% for GIFT in combination with IVF/ET (based on 199 oocyte retrievals), 8% for frozen embryo transfers (based on 490 transfer cycles), and 17% for IVF/ET with donated oocytes (based on 60 donor oocyte transfers).

In each of the publications, we presented limited case reports on all reported congenital malformations and chromosomal abnormalities. Due to the relatively small numbers of cases observed to date, we have not yet prepared a separate publication investigating their occurrence. However, we constantly monitor the database for potentially important adverse effects warranting publication in the medical literature.

We believe that the Registry can now begin to act as a resource from which selected preliminary results can be published. The statistics contained in the most recent publication reflect both the interests of practitioners and public health researchers. As the patient-specific database grows, it will contain a wealth of patient, treatment, laboratory, and outcome results that will be shared with the health care community.

A major concern of the Registry is the quality of the information submitted to it by member clinics - both in terms of completeness and accuracy. Concerns have been raised regarding several potential forms of bias that could affect the validity of the Registry's results. After all, the Registry has limited resources and can not send trained "auditors" around the country to each and every Registry clinic - if indeed that is a feasible strategy, which I do not think it is. So what makes us believe that the Registry's efforts result in useful and valuable statistics?

The Registry's voluntary and confidential data collection methodology not only helps to optimize clinic enrollment and cooperation, but it also helps to minimize biased reporting. Since individual clinics are not identified in any of the Registry's publications they are neither "rewarded" nor "penalized" by their reported levels of "success" or "failure." There appear to be no incentives for individual clinics to submit false data or to selectively report only certain types of patients and/or outcomes. This traditional approach to guaranteeing the integrity of research information remains a fundamental Registry strategy.

Alternatively, one would have to argue that there is collusion among a subset of clinics to submit false data. This appears unrealistic for several reasons, chiefly the incredibly complex and time-consuming task from both statistical and computing perspectives.

Since the last publication, we have issued our first request for

1988 data. Although the information is only now being returned, the number of clinics using MRI's software has increased and correspondingly the number of patient-treatment cycles reported via computer appears to have increased.

Also, the Registry's design and methodology played a major role in MRI receiving the NICHD award to conduct the follow-up study of women undergoing the assisted reproductive technologies. As is normal in such situations, the scope and quality of the Registry's data collection methods was peer reviewed by an independent panel prior to the award. We believe that this approval lends credibility to the Registry's overall research design. Aside from two fundamental modifications, the Registry's methodology is being applied directly in this epidemiologic investigation.

The two modifications warrant mention in the present context. The first allowed us to recruit a nurse coordinator to visit each of the nine participating clinics to insure data quality. The second, reflecting the follow-up nature of the NICHD study, enables us to systematically monitor the health status of the women over time.

We continue to receive several inquiries a week regarding membership, and each week we approach our goal of monitoring all U.S. clinics estimated to number approximately 200. Of the current 155 U.S. members, some 85 (55%) are members of SART, and it is expected that this percentage will only increase with time. These 85 clinics, however, account for approximately 80-85% of the Registry's patient-stimulation cycles.

As the Registry continues to expand, I can envision several important new initiatives that it might take. One new would be a separate research effort to enroll and monitor the growth and development patterns of the offspring resulting from the assisted reproductive technologies. Currently, the Registry restricts its limited observations on the offspring to those recorded congenital malformations and chromosomal abnormalities detected at birth. We do not have the financial resources to perform a follow-up study analogous to the one being conducted on the patients.

Another new responsibility would be to have the Registry act as the coordinating site for large multicenter intervention clinical trials aimed at testing the relative efficacy of innovative assisted reproductive technologies.

However, as with similar research programs, its future value relies on the critical support of: 1) the physicians and staffs at the clinics delivering assisted reproductive technology medical care, 2) the AFS and SART, 3) on our current funding sources - Serono for the Registry, and the NICHD - for the follow-up study, and 4) the patients and their community-based advocacy organizations, such as RESOLVE.

In closing, I would like to convey the enthusiasm and commitment that we at MRI have in carrying out the Registry's mission, and in seeking ways to insure that it plays a meaningful role in measuring the future contributions of the assisted reproductive technologies.

APPENDIX

In vitro fertilization/embryo transfer in the United States: 1985/1986 AND 1987 results from the National IVF-ET Registry

(Reprints of articles published in "Fertility & Sterility")

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In vitro fertilization/embryo transfer in the United States: 1985 and 1986 results from the National IVF/ET Registry*†

Medical Research International‡
The American Fertility Society Special Interest Group

Lexington, Massachusetts and Birmingham, Alabama

This is the first report of the United States Registry of in vitro fertilization/embryo transfer (IVF/ET) and related practices. Summary data from 1985 and 1986, collected from retrospective reporting, are presented. There were 2389 and 2864 IVF cycles with embryos transferred in 1985 and 1986, respectively. In 1985 and 1986, 337 (14.1%) and 485 (16.9%) of the transfer cycles, respectively, resulted in clinical pregnancies. The number of cycles with frozen embryos transferred increased from 26 to 112 between 1985 and 1986. In 1986, there were 7 clinical pregnancies through frozen ET. In 1985, there were 56 gamete intrafallopian transfer (GIFT) procedures, whereas in 1986 there were 460 such treatment cycles. The number of clinical pregnancies by GIFT increased from 3 to 108 between 1985 and 1986. Fertil Steril 49:212, 1988

In recent years, in vitro fertilization/embryo transfer (IVF/ET) practice has gained widespread acceptance and, as a result, the number of patients seeking and receiving treatment has increased greatly. To better evaluate IVF/ET and related infertility therapies, The American Fertility Society's (AFS) Society of Assisted Alternative Reproductive Technology and Medical Research International (MRI) designed and developed a registry of patients treated by IVF/ET clinics in the United States and overseas.

The IVF/ET Registry seeks the following: (1) to document rates of pregnancy and selected birth outcomes, (2) to identify optimal treatment profiles for different patient groups, and (3) to act as a follow-up program capable of detecting and measuring possible short- and long-term adverse health effects on women and their offspring.

MATERIALS AND METHODS

Since its initiation in the fall of 1986, the Registry has enrolled 103 United States and foreign clinics. The majority of these clinics joined the Registry within the last 6 months. AFS-SIG clinics automatically qualify as members of the Registry, and are required to submit their data on a regular basis.

When data collection was instituted in 1987, clinics were required to submit summary data for 1986 and earlier on a specially designed data form. Forty-one clinics provided the 1986 summary information requested on the data forms. Thirty of these clinics also provided the corresponding 1985 summary data.

Since the purpose of this report is to present descriptive information summarizing the experience of United States IVF/ET clinics, hypothesis testing and inferential statistical techniques were not considered appropriate.

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RESULTS

In Vitro Fertilization and Embryo Transfer

In 1986, the 41 reporting clinics treated 3055 different patients, an increase of 580 patients (23.4%) over 1985. The median number of patients, however, decreased by 24.2% from 62 in 1985 to 47 in 1986, which can be explained, in part, by the increase in smaller volume clinics. For example, in 1986, there were ten clinics that treated 20 or fewer patients, and nine that treated 100 or more patients. In comparison, in 1985, there were four clinics that treated 20 or fewer patients, and eight that treated 100 or more patients.

A reported 4867 stimulation cycles were performed in 1986, an increase of 946 (24.1%) over 1985; however, the median number of cycles performed per clinic decreased from 83 to 69 from 1985 to 1986.

The most common stimulation therapies reported were "human menopausal gonadotropin (hMG) alone" by 13 and 20 clinics, and "hMG with clomiphene citrate" by 16 and 20 clinics in 1985 and 1986, respectively. The combination of hMG and follicle-stimulating hormone (FSH) was used most often by one clinic in each year. The clinics reported that there were 6 patients hospitalized for hyperstimulation in both 1985 and 1986, with corresponding hyperstimulation rates of 1.5 and 1.2 patients per 1000 stimulation cycles.

In 1985 and 1986, the median rates of attempted oocyte retrieval per clinic, expressed as a rate of stimulation cycles culminating in an attempted retrieval, were 75 and 72%, respectively. In 1985, the reported 2724 laparoscopies represented 94.2% of all retrieval operations. Whereas, in 1986, the 2632 laparoscopies represented 78.2% of such procedures.

In 1985, 9 clinics performed 166 ultrasound retrievals; in 1986, 20 clinics performed 725 ultrasound retrievals.

There were 2389 and 2864 ET cycles in 1985 and 1986, respectively. The median number of transfer cycles decreased from 56 per clinic in 1985 to 30 per clinic in 1986. Furthermore, 83% in 1985, and 85% in 1986 of retrieval cycles resulted in an ET. In 1985 and 1986, the respective median numbers of embryos transferred per transfer cycle were 2.8 and 3.0, respectively.

In 1985, 337 (14.1%) cycles in which an embryo was transferred resulted in a clinical pregnancy (positive fetal heart documented by ultrasound). In 1986, clinical pregnancies increased to 485 (16.9%) of the transfer cycles. Table 1 presents the mean clinical pregnancy rates by the number of transfer cycles. In this table, these cycles have been stratified by number of transfers per clinic using intervals whose cutoff points approximate the quartile values. The pregnancy outcomes related to IVF/ET are given in Table 2.

Table 1 Clinical Pregnancy Rates (%) by Annual Number of Embryo Transfer Cycles per IVF/ET Clinic in 1985 and 1986

No. embryo transfer cycles	No. clinical pregnancies	Clinical pregnancy rate
1985		
		%
<20	11	14.5
21–56	28	9.1
57–80	72	16.1
>80	226	14.8
1986		
<16	6	8.8
16–30	33	13.3
31–80	99	16.9
>80	347	17.7

Table 3 lists the reported chromosomal abnormalities and congenital anomalies.

Frozen Embryo Transfers

In 1985, nine clinics treated 105 IVF patients whose stimulation cycles resulted in freezing some of their embryos. For the 105 patients, a total of 289 or approximately 2.8 embryos per patient were frozen. Frozen embryos were replaced in 26 treatment cycles.

By comparison, 15 clinics in 1986 treated 319 patients whose stimulation cycles resulted in freezing some of their embryos. For the 319 patients, a total of 824 (285% more than the previous year) and a median of approximately 2.8 embryos per patient were frozen. Frozen embryos were replaced in 112 treatment cycles, a 431% increase over the previous year. In 1986, there were seven clinical pregnancies in 3 of the 15 clinics transferring frozen embryos, with a clinical pregnancy rate ranging from 10.5% to 11.1% per transfer procedure. There were no clinical pregnancies reported for 1985.

Table 2 presents the pregnancy outcomes related to frozen embryo transfers. No chromosomal abnormalities or congenital anomalies were reported.

Table 2 Pregnancy Outcomes Related to IVF/ET, Frozen Embryo, and GIFT Procedures

Pregnancy outcomes	IVF/ET		Frozen embryo		GIFT	
	1985	1986	1985	1986	1985	1986
Ectopic pregnancies						
No.	20	22	0	0	0	7
Rate[a]	5.9	4.5	—	—	—	6.5
Abortions						
No.	140	151	0	1	1	24
Rate[a]	41.5	31.1	—	14.3	33.3	22.2
Stillborn						
No.	4	5	0	0	0	0
Rate[a]	1.2	1.0	—	—	—	—
No. liveborn						
Males	137	174	0	3	2	31
Females	120	137	0	3	1	32

[a] Rate expressed per 100 clinical pregnancies.

Gamete Intrafallopian Transfer

In 1985, eight clinics reported performing gamete intrafallopian transfer (GIFT) in 47 patients. Only two clinics performed the procedure in 10 or more patients. A total of 56 GIFT cycles were performed in 1985. The number of GIFT patients increased almost 9-fold in 1986 to 419. These patients were treated in 25 clinics, 11 of which performed the procedure in 10 or more patients. The clinics performed 466 GIFT cycles in 1986.

There were 3 and 108 clinical pregnancies in 1985 and 1986, respectively. Thus, the corresponding clinical pregnancy rates were 5.4 and 23.2% of the GIFT treatment cycles, respectively. Table 2 presents the pregnancy outcomes related to the GIFT procedures. No chromosomal abnormalities or congenital anomalies were reported.

Table 3 Chromosomal Abnormalities and Congenital Anomalies Reported in IVF/ET

A. 1985—Chromosomal abnormalities
Case 1 Trisomy 18

B. 1985—Congenital anomalies[a]
Case 1 Congenital cordi penis
Case 2 Diaphragmatic hernia

C. 1986—Chromosomal abnormalities
Case 1 Trisomy 13
Case 2 Klinefelter's syndrome
Case 3 Turner's syndrome

D. 1986—Congenital anomalies[b]
Case 1 Undescended testicle
Case 2 Spina bifida
Case 3 Imperforate anus, ambiguous genitalia (died after birth)
Case 4 Polycystic kidney
Case 5 Choanal atresia
Case 6 Dandy Walker syndrome
Case 7 Hyperplastic left ventricle
Case 8 Cat's eye pupil
Case 9 Encephalocele, long bone of forearm missing

[a] One infant was diagnosed with cerebral palsy at 12 months of age, and one infant suffered a cerebral hemorrhage thought to be secondary to intrapartum asphyxia.

[b] One premature infant suffered a cerebral hemorrhage, and died at 1 week after birth.

In Vitro Fertilization of Donated Oocytes

Of the 41 clinics reporting their treatment procedure and outcome information in 1985 and 1986, only 1 reported performing IVF/ET with donated oocytes. For the 2-year period, this clinic performed a total of 32 embryo transfers using donated oocytes. These transfers resulted in eight clinical pregnancies, and five liveborns (three males and two females). No chromosomal abnormalities or congenital anomalies were observed in the offspring.

DISCUSSION

The 1985 and 1986 summary results represent the first report of the United States Registry of IVF/ET and related practices. These statistics, however, should be interpreted with caution, due mainly to the restrictive nature of the data collection forms used. These forms were completed through a retrospective review of clinic records. In addition, it was not possible to link individual patients/cycles across the 2 reporting years. For example, some clinics reported births in the year in which pregnancy was initiated, and others reported births in the year in which delivery occurred.

In addition to using more intensive automated prospective data collection procedures, the Registry plans to present future reports using statistical techniques, such as longitudinal data analysis.

COMMENT

This report is the first data that has been collected, analyzed, and published from the National IVF registry which was organized by Medical Research International and the American Fertility Society IVF Special Interest group and totally supported by Serono Laboratories, Braintree, Massachusetts. The material contained in this manuscript is the first attempt at analyzing the recent clinical outcomes from selected centers in the United States performing IVF, GIFT, embryo freezing, and related procedures. The information contained within is critical for the medical community to scrutinize and helpful for the lay public to better understand the problem of less than optimal outcome persisting within these technologies. This report is not a complete analysis of all IVF, GIFT and frozen embryo work performed in the United States but in the future, would be the Registry's goal to eventually be able to report on all work done with these advanced technologies.

Richard P. Marrs, M.D.
Past President,
IVF-SIG

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In vitro fertilization/embryo transfer in the United States: 1987 results from the National IVF-ET Registry*

Medical Research International† and the Society of Assisted Reproductive Technology,
The American Fertility Society

Burlington, Massachusetts and Birmingham, Alabama

This is the second annual report of the U.S. Registry of IVF-ET and related practices. The present report describes the 1987 experiences of 96 U.S. member clinics with respect to treatments and outcomes. During 1987, 14,647 in vitro fertilization (IVF) and/or gamete intrafallopian transfer (GIFT) stimulation cycles were performed; there were 490 frozen embryo and 60 donor oocyte transfers. Ninety percent of the clinics had at least one delivery, and overall, a total of 1858 babies were born. The overall clinical pregnancy rates were 16% for IVF (based on 8725 retrievals), 25% for GIFT (based on 1968 retrievals), and 28% for IVF and GIFT in combination (based on 199 retrievals). The results for each procedure are described in detail. Fertil Steril 51:13, 1989

In 1982, it was estimated that approximately 2.4 million (8.5%) married couples in the U.S. were infertile.[1] The high prevalence and health care costs related to this disorder are now well recognized.[1]

Over the last decade, in vitro fertilization (IVF), embryo transfer (ET), gamete intrafallopian transfer (GIFT), and a variety of related assisted reproductive technologies (all referred herein as IVF-ET) have emerged as increasingly important treatments for infertility.

To better understand IVF-ET practice and its results, the United States IVF-ET Registry was established as a collaborative effort between The Society of Assisted Reproductive Technology (SART) and Medical Research International (MRI). The Registry's data collection efforts were implemented in January 1987, and its first report summarized the 1985 and 1986 practices and results from 41 U.S. clinics.[2]

Since the preparation of its initial report, the Registry's U.S. membership has increased to 119 clinics in 38 states, the District of Columbia, and Puerto Rico; of these clinics, more than 50 enrolled in 1988. This report describes the 1987 IVF-ET practices and outcomes of 96 U.S. member clinics (listed below).

The Registry's current reporting period included stimulation cycles initiated in the 1987 calender year. In addition, 1987 pregnancies were followed to determine their outcome status as of November 1988.

MATERIALS AND METHODS

Selected information on all IVF-ET patients being treated by member clinics are recorded and sent to the Registry's offices (MRI) for quality review, data management, and statistical analysis.

Registry members collect and forward their data using either (1) a PC-based system, "RecordKeeper," designed specifically for IVF-ET clinics, or (2) a set of data forms that summarizes each clinic's treatment and outcome results. On enrollment into the Registry, a clinic is required to submit retrospective data (prior years' experiences) via the data forms, and to begin prospective data

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Table 1 IVF Treatment Outcome by Number of Retrieval Cycles Performed

Retrieval cycles	No. clinics	Total no. retrievals	Clinical pregnancies[a]		Abortions[b]		Ectopic pregnancies[c]		All deliveries[d]		Multiple deliveries[e]	
			No.	%	No.	%	No.	%	No.	%	No.	%
<25	30	392	51	13	16	31	2	4	34	9	9	2.4
25–99	38	1983	266	13	59	22	23	8	196	10	47	2.4
100–199	19	2602	408	16	115	28	24	6	286	11	64	2.5
>199	9	3748	642	17	154	24	54	8	476	13	115	3.1
Total	96	8725	1367	16	344	25	103	7	991	11	235	2.7

[a] Clinical pregnancy rates are expressed as a percentage of retrievals.

[b] Spontaneous abortion rates are expressed as a percentage of clinical pregnancies.

[c] Ectopic pregnancy rates are expressed as a percentage of all pregnancies (clinical and ectopic).

[d] All (live) delivery rates are expressed as a percentage of retrievals.

[e] Multiple delivery rates are expressed as a percentage of retrievals.

collection and submission using "RecordKeeper." Until access is available, clinics without computers can continue to use the data forms for prospective data submission.

The data forms provide the Registry with an overall summary of a clinic's activities. Among the information collected are annual total numbers of: patients, cycles, retrieval procedures, oocytes retrieved, transfer procedures, pregnancies, and pregnancy outcomes, including congenital anomalies and chromosomal abnormalities.

Unlike the data forms, "RecordKeeper" allows clinics to record patient- and cycle-specific information, including: patient vital statistics, reproductive history of both patient and spouse/donor, medical and drug history, laboratory results, ovulation induction treatments, retrieval, fertilization and transfer procedures, luteal phase support, pregnancy monitoring and outcome, congenital anomalies, and chromosomal abnormalities, and any adverse events. The floppy disks containing these data are sent to the Registry's offices for processing and analysis.

Although a minimum of 60 member clinics have begun using "RecordKeeper," only 24 were prepared to submit quality reviewed data to the Registry for the current report; the remaining clinics forwarded their information via the data forms.

The treatments and the results for IVF-ET cycles initiated in 1987 are presented either (1) as summary statistics using the pooled results from both data forms and floppy disks, or (2) as more detailed analyses using the individual patient records submitted via disks only. Unless stated otherwise, each analysis is based on the pooled results combining both paper form and disk information.

RESULTS

This report describes the results obtained for the following four major treatment categories: IVF,

Table 2 IVF Treatment Outcome by Number of Transfer Cycles Performed

Transfer cycles	No. clinics	Total no. transfers	Clinical pregnancies[a]		Abortions[b]		Ectopic pregnancies[c]		All deliveries[d]		Multiple deliveries[e]	
			No.	%	No.	%	No.	%	No.	%	No.	%
<25	35	422	69	16	20	29	2	3	45	11	11	2.6
25–99	38	2052	315	15	77	24	27	8	228	11	54	2.6
100–199	16	2185	408	19	103	25	28	6	296	13	67	3.1
>199	7	2902	575	20	144	25	46	7	422	15	103	3.6
Total	96	7561	1367	18	344	25	103	7	991	13	235	3.1

[a] Clinical pregnancy rates are expressed as a percentage of transfers.

[b] Spontaneous abortion rates are expressed as a percentage of clinical pregnancies.

[c] Ectopic pregnancy rates are expressed as a percentage of all pregnancies (clinical and ectopic).

[d] All (live) delivery rates are expressed as a percentage of transfers.

[e] Multiple delivery rates are expressed as a percentage of transfers.

Table 3 Chromosomal Abnormalities and Congenital Anomalies Reported in IVF-ET

Case	Diagnosis	Maternal age (yrs)	Outcome
In Vitro Fertilization (IVF)			
A. Chromosomal Abnormalities			
1	Trisomy 13	39	Therapeutic abortion
2	Trisomy 18	28	Therapeutic abortion
3	Trisomy 18	35	Therapeutic abortion
4	Trisomy 21	28	Stillborn
5	Trisomy 21	41	Therapeutic abortion
6	Trisomy 21	34	Liveborn
7	Trisomy 17	40	Spontaneous abortion
8	Tay-Sachs	35	Therapeutic abortion
9	Triploidy Syndrome	unk.	Spontaneous abortion
B. Congenital Anomalies			
1	Hydrocephaly	36	Liveborn
2	Anencephaly	33	Therapeutic abortion
3	Pfeiffer Syndrome	34	Liveborn
4	Transposition of great vessels	37	Expired
5	Anomalous pulmonary venous connection	37	Liveborn
6	Spina bifida	35	Expired
7	Klinefelter Syndrome	36	Liveborn
8	Hypospadias	31	Liveborn
9	Webb fingers	unk.	Liveborn
10	Imperforate anus	unk.	Liveborn
Gamete Intrafallopian Transfer (GIFT)			
A. Chromosomal Abnormalities			
1	Trisomy 21	>35	Therapeutic abortion
B. Congenital Anomalies			
1	Microcephaly	22	Therapeutic abortion
2	A/V septal defect	35	Liveborn
3	Cleft lip	25	Liveborn
4	Tetralogy of fallot	36	Liveborn
IVF & GIFT Combined			
A. Congenital Anomalies			
1	Testicular hydrocele	31	Liveborn
Donor Oocyte			
A. Chromosomal Abnormalities			
1	Trisomy mosaic triploid	26 (donor)	Spontaneous abortion
B. Congenital Anomalies			
1	Epstein's Cardiac Anomaly	unk.	Stillborn

GIFT, frozen embryo transfers, and donor transfers.

Altogether, in 1987, the 96 IVF-ET clinics enrolled 10,397 patients, and initiated a total of 14,647 stimulation cycles, of which 73.9% (10,818) resulted in oocytes being retrieved. Among the 96 clinics, 86 (90%) reported at least one delivery resulting from an IVF-ET procedure.

These treatments, as described below, resulted in an overall total of 1858 babies and 17 clinical pregnancies, whose outcome status was unknown to the Registry as of November 1988. For babies whose sex was known, the male:female ratio was 806:832 or 0.97.

The data forms summarized IVF-ET treatment and results on 8462 patients, and the "Record-Keeper" disks contained patient- and cycle-specific information on 1935 patients.

In Vitro Fertilization (IVF)

In 1987, each of the 96 clinics reported performing IVF. For all clinics, 8725 IVF retrievals were performed, of which 3619 (41%) were by laparoscopy, 4990 (57%) were by ultrasound, 97 (1%) were by a combination of laparoscopy and ultrasound, and the remainder were by laparotomy.

Tables 1 and 2 give the distributions of selected outcomes related to IVF retrievals and transfers, respectively. Eighty-seven percent of retrieval cycles resulted in an embryo transfer. In addition, there were 11 clinical pregnancies whose outcomes were unknown. The maximum numbers of reported IVF retrievals and transfers were 706 and 614, respectively.

A total of 1367 clinical pregnancies (defined by rising beta human chorionic gonadotropin [β-hCG] and the presence of gestational sac(s) on ultrasound) were conceived as a result of an IVF treatment. Four clinics accounted for 451 (33%) of all clinical pregnancies; 60 (62%) of the clinics reported less than 10 pregnancies, while overall 87 (91%) clinics reported at least 1 clinical pregnancy using an IVF treatment.

Nine hundred ninety-one (72.5%) of the clinical pregnancies resulted in live deliveries, of which 13% were considered preterm. The Registry records deliveries (preterm, births occurring before 36 weeks gestation; term, births occurring thereafter) in the reporting year in which conception occurred.

Among the 13 clinics not reporting a delivery, the maximum number of retrievals was 26. Four clinics accounted for 34% of the deliveries as a result of IVF. Also, 41 (43%), 31 (32%), and 11 (11%) of the clinics had delivery rates per retrieval between 1 and 9%, 10 and 19%, and 20 and 38%, respectively. The clinic reporting the maximum 38% delivery rate performed 8 retrievals. Ten clinics performed 3934 oocyte retrievals, resulting in 492 (50%) deliveries.

There were 1260 babies born, including 511 re-

Table 4 IVF Treatment Outcome by Number of Fresh Embryos Transferred

No. embryos transferred	No. transfer cycles	Clinical pregnancies[a]		Abortions[b]		Ectopic pregnancies[c]		All deliveries[d]		Multiple deliveries[e]	
		No.	%	No.	%	No.	%	No.	%	No.	%
0	175	0	0	—		—		—		—	
1	212	17	8	4	24	1	6	12	6	0	0.0
2	270	50	19	13	26	7	12	31	11	1	f
3	310	67	22	19	28	10	13	38	12	8	2.6
4	336	86	26	18	21	9	9	60	18	10	3.0
5	213	58	27	14	24	6	9	36	17	12	5.6
6	45	9	20	0	0	1	10	8	18	4	8.9
7	22	6	27	0	0	1	14	4	18	2	9.1
8	7	1	14	0	0	0	0	1	14	1	14.3
9+	5	0	0	0	0	0	0	0	0	0	0.0
Total	1600	296	18	66	22	35	10	198	12	38	2.4

[a] Clinical pregnancy rates are expressed as a percentage of embryo transfer cycles.

[b] Spontaneous abortion rates are expressed as a percentage of clinical pregnancies.

[c] Ectopic pregnancy rates are expressed as a percentage of all pregnancies (clinical and ectopic).

[d] All (live) delivery rates are expressed as a percentage of embryo transfer cycles.

[e] Multiple delivery rates are expressed as a percentage of embryo transfer cycles.

[f] Less than 0.1%.

sulting from 235 multiple births. Overall, 17.2% of the clinical pregnancies resulted in a multiple delivery, and 2.8% ended in triplets or greater.

In addition to the 344 reported (spontaneous) abortions given in Table 1, there were 14 stillbirths and 14 therapeutic abortions recorded. The Registry defines a (spontaneous) abortion as a clinical pregnancy loss occurring before a gestational age of 20 weeks, a stillbirth as a birth of a nonviable fetus of 20 weeks gestation or more.

The relationships between the number of fresh embryos replaced during IVF and selected outcomes are given in Table 4. These data summarize 1600 transfer cycles that were recorded by the 24 clinics using "RecordKeeper."

The corresponding spontaneous abortion rate for 1 to 5 embryos replaced ranged from a low of 21% (for 4 transferred) to 28% (for 3 transferred). There were no spontaneous abortions for six or more embryos transferred.

Table 3 lists the cases of therapeutic abortion together with the reported congenital anomalies and chromosomal abnormalities.

Gamete Intrafallopian Transfer (GIFT)

There were 71 clinics that performed gamete intrafallopian transfers (GIFT) alone. Table 5 gives the treatment results by number of GIFT retrieval cycles. (There were 6 clinical pregnancies, whose outcomes were unknown as of November, 1988).

A total of 1968 GIFT retrievals were reported, of which 1628 (83%) were by laparoscopy, 217 (11%) were by laparotomy, and 123 (7%) were by ultrasound.

Table 5 GIFT Outcome by Total Number of GIFT Retrievals Performed

GIFT cycles	No. clinics	No. GIFT retrievals	Clinical pregnancies[a]		Abortions[b]		Ectopic pregnancies[c]		All deliveries[d]		Multiple deliveries[e]	
			No.	%	No.	%	No.	%	No.	%	No.	%
<25	54	397	90	23	29	32	7	7	60	16	18	4.5
25–99	9	323	52	16	12	23	4	7	37	11	6	1.9
>99	8	1248	350	28	75	21	19	5	265	21	79	6.3
Total	71	1968	492	25	116	24	30	6	362	18	103	5.2

[a] Clinical pregnancy rates are expressed as a percentage of retrievals.

[b] Spontaneous abortion rates are expressed as a percentage of clinical pregnancies.

[c] Ectopic pregnancy rates are expressed as a percentage of all pregnancies (clinical and ectopic).

[d] All (live) delivery rates are expressed as a percentage of retrievals.

[e] Multiple delivery rates are expressed as a percentage of retrievals.

Table 6 Treatment Outcome by Number of Frozen Embryo Transfer Cycles

Frozen embryo transfer cycles	No. clinics	No. transfer cycles	Clinical pregnancies[a]		Abortions[b]		Ectopic pregnancies[c]		All deliveries[d]		Multiple deliveries[e]	
			No.	%	No.	%	No.	%	No.	%	No.	%
<25	33	197	18	9	6	33	1	5	12	6	1	0.5
25–49	3	86	4	5	0	0	0	0	4	5	0	0.0
50–99	3	208	28	13	6	21	0	0	22	11	5	2.4
Total	39	490	50	10	12	24	1	2	38	8	6	1.2

[a] Clinical pregnancy rates are expressed as a percentage of embryo transfer cycles.

[b] Spontaneous abortion rates are expressed as a percentage of clinical pregnancies.

[c] Ectopic pregnancy rates are expressed as a percentage of all pregnancies (clinical and ectopic).

[d] All (live) delivery rates are expressed as a percentage of embryo transfer cycles.

[e] Multiple (live) delivery rates are expressed as a percentage of embryo transfer cycles.

There were 29 (41%) clinics that did not report a delivery; however the maximum number of retrievals performed in this group was 16. Excluding clinics with less than 3 retrievals, the maximum observed delivery rate was 35%, 18 clinics had delivery rates between 20 and 29%, 19 clinics had delivery rates between 10 and 19%, and 16 clinics had delivery rates below 10%. Two clinics reported more than 200 GIFT treatments.

Altogether, there were 492 (25%) clinical pregnancies conceived through the GIFT procedure. Fifty clinics had at least 1 clinical pregnancy, and of these, 39 had less than 10 pregnancies. There were 4 clinics that had 40 or more GIFT pregnancies, accounting for 43% of the total number reported.

The spontaneous abortion rate associated with GIFT was 24%. In addition, there were seven therapeutic abortions, two of which were attributed to chromosomal abnormalities and congenital anomalies (Table 3). Four stillbirths also were noted.

Forty-seven (66%) of the clinics performing GIFT had a total of 362 deliveries, and 8 of these clinics accounted for 265 (73%) of the deliveries. A total of 489 babies were delivered, including 82 twins, and 21 sets of triplets or others. In addition, there was a 10% preterm delivery rate associated with the GIFT procedure.

Gamete Intrafallopian Transfer (GIFT) in Combination with In Vitro Fertilization (IVF)

Eighteen of the 96 clinics reported using GIFT in combination with IVF in a total of 199 oocyte retrievals, resulting in 55 (28%) clinical pregnancies and 40 (20%) deliveries. Five of the clinics performed 77% of the combined procedures. Ninety-six percent (192) of the retrievals were performed using laparoscopy.

Eight clinics delivered all 49 babies, including eight sets of twins and one set of triplets. In addition, there was a 15% preterm delivery rate associated with the use of the combination treatment.

There was one reported congenital anomaly but no chromosomal abnormalities associated with the combination treatment (Table 3).

Frozen Embryo Transfers

There were 490 frozen embryo transfer cycles in 39 of the reporting clinics. Three of the clinics performed 50 to 100 such cycles, accounting for 56% of the clinical pregnancies, and 58% of the deliveries. Sixteen (41%) of the clinics had at least one clinical pregnancy. Table 6 details the distribution of selected outcomes by number of frozen embryo transfer cycles. In addition, there were 1186 patients whose IVF cycles resulted in freezing 3715 embryos, or 3.13 per patient.

Donated Oocytes

In 1987, 17 clinics returned data indicating that they performed IVF-ET with donated oocytes. Forty-nine patients underwent a total of 60 donor transfers. Twelve (20%) of the transfers resulted in a clinical pregnancy, 1 of which ended in a spontaneous abortion and 1 of a triplet delivery was stillborn. Among the 10 deliveries, 8 were term and 2 were preterm, and 4 were multiple deliveries. Altogether, there 16 babies born through the use of donated oocytes.

DISCUSSION

The current report describes the IVF-ET practices of 96 reporting clinics in the U.S. who are members of the national Registry. In the previous report, which profiled 1985 to 1986, results were based on 41 reporting clinics. The growth in the Registry's membership reflects, in part, the increasing interest of the clinical community in helping to better understand the nature and results related to these sophisticated forms of reproductive therapy.

In addition, the number of IVF-ET clinics recording and submitting their clinical data to the Registry using a specially designed PC-based software system ("RecordKeeper") continues to grow. Because the software records patient-specific information in detail, the Registry's database is a valuable resource for exploring the epidemiology of IVF-ET practice and its outcomes.

Acknowledgments. Medical Research International would like to express its appreciation to the staffs at the following clinics for their critical support of the IVF-ET Registry. These clinics contributed data as of October 1, 1988: Akron City Hospital, Akron, Ohio; Albert Einstein College of Medicine, Dobbs Ferry, New York; Albert Einstein Medical Center, Northern Division, Philadelphia, Pennsylvania; Alta Bates Hospital, Berkeley, California; AMI South Bay Hospital, Redondo Beach, California; Appleton Medical Center, Appleton, Wisconsin; Augusta Reproductive Biology Associates, Augusta, Georgia; Baylor Reproductive Research Laboratory, Houston, Texas; Bennett Fertility Institute, Oklahoma City, Oklahoma; Beth Israel Hospital, Boston, Massachusetts; Bethesda Fertility Center, Cincinnati, Ohio; Blodgett Memorial Medical Center, Grand Rapids, Michigan; Boston IVF, Brookline, Massachusetts; Brigham and Women's Hospital, Boston, Massachusetts; Center for Fertility and Reproductive Medicine, Newark, New Jersey; Center for Reproductive Medicine, Wichita, Kansas; Center for Reproductive Medicine, Charlotte, North Carolina; Century City IVF Laboratory, Los Angeles, California; Cleveland Clinic, Cleveland, Ohio; Columbia Hospital for Women Medical Center, Washington, DC; Cornell University Medical Center, New York, New York; Dartmouth Hitchcock Medical Center, Hanover, New Hampshire; Duke University Medical Center, Durham, North Carolina; Fertility Clinic of Puget Sound, Tacoma, Washington; Fertility Institute, Fort Thomas, Kentucky; Fertility Institute of New Orleans, New Orleans, Louisiana; Fertility Institute of Northwest Florida, Gulf Breeze, Florida; Fort Worth Infertility Center, Fort Worth, Texas; Genetics & IVF Institute, Fairfax, Virginia; George Washington University Medical Center, Washington, D.C.; Greater Boston In-Vitro Associates, Newton, Massachusetts; Hillcrest Fertility Center, Tulsa, Oklahoma; HOAG Fertility Service Center, Newport Beach, California; Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania; Humana Women's Hospital, Tampa, Florida; Indianapolis Fertility Center, Indianapolis, Indiana; Institute for Reproductive Medicine, Hospital for the Good Samaritan, Los Angeles, California; IVF Australia at Birmingham, Birmingham, Alabama; IVF Australia Program at United Hospital, Port Chester, New York; IVF Illinois, Chicago, Illinois; Jewish Hospital of St. Louis, St. Louis, Missouri; John Muir Hospital, Walnut Creek, California; Johns Hopkins Hospital, Baltimore, Maryland; Jones Institute, Norfolk, Virginia; Mayo Clinic, Rochester, Minnesota; Medical College of Georgia, Augusta, Georgia; Medical College of Virginia, Richmond, Virginia; Medical University of South Carolina Hospital, Charleston, South Carolina; Methodist Hospital, Indianapolis, Indiana; Michael Reese Medical Center, Chicago, Illinois; Midwest Reproductive Institute, Columbus, Ohio; Montgomery Infertility Institute, Bethesda, Maryland; Mount Sinai Medical Center, New York, New York; Mount Sinai Hospital, Chicago, Illinois; Northwest Center for Infertility, Margate, Florida; Northern Nevada Fertility, Reno, Nevada; Northridge Hospital, Northridge, California; Norton Hospital, Louisville, Kentucky; Nova Fertility Center, San Mateo, California; Methodist Hospital IVF Program, Omaha, Nebraska; Ohio State University, Columbus, Ohio; Oregon Health Sciences Center, Portland, Oregon; Pennsylvania Hospital, Philadelphia, Pennsylvania; Presbyterian Hospital, Albuquerque, New Mexico; Reproductive Biology Associates, Atlanta, Georgia; Reproductive Genetics Center, Denver, Colorado; Richmond Center for Fertility & Endocrinology, Richmond, Virginia; Robert Wood Johnson Medical School, New Brunswick, New Jersey; Rush-Presbyterian/St. Luke's Medical Center, Chicago, Illinois; Saginaw General Hospital, Saginaw, Michigan; St. David's Community Hospital, Austin, Texas; Sand Lake Hospital, Orlando, Florida; Scripps Clinic Fertility Center, La Jolla, California; Shadyside Hospital, Pittsburgh, Pennsylvania; Shands Hospital, Gainesville, Florida; Southeastern Fertility Center, Mount Pleasant, South Carolina; Texas Endocrine and Fertility Institute, Carrollton, Texas; UCI/AMI Center for Reproductive Health, Garden Grove, California; University of Alabama, Birmingham, Alabama; University of California at Irvine, Long Beach, California; University of California at San Francisco, San Francisco, California; University of Iowa Hospitals and Clinics, Iowa City, Iowa; University of Minnesota, Minneapolis, Minnesota; University of Mississippi, Jackson, Mississippi; University of North Carolina, Chapel Hill, North Carolina; University of Rochester, Rochester, New York; University of Southern California School of Medicine, Los Angeles, California; University of Tennessee, Knoxville, Tennessee; University of Texas Health Science Center, Dallas, Texas; University of Texas Medical School, Houston, Texas; University of Utah, Salt Lake City, Utah; University of Washington, Seattle, Washington; University of Wisconsin, Madison, Wisconsin; Vanderbilt University, Nashville, Tennessee; Wayne State University/Hutzel Hospital, Detroit, Michigan; William Beaumont Hospital, Royal Oak, Michigan; Women & Infants' Hospital, Providence, Rhode Island; Women's Clinic Ltd., Reading, Pennsylvania; Yale University Medical Center, New Haven, Connecticut.

REFERENCES

1. U.S. Congress, Office of Technology Assessment: Infertility: Medical and Social Choices. OTA-BA-358, Washington, D.C., U.S. Government Printing Office, May 1988
2. Medical Research International, The American Fertility Society Special Interest Group: In vitro fertilization/embryo transfer in the United States: 1985 and 1986 results from the National IVF-ET Registry. Fertil Steril 49:212, 1988

COMMENT

This is the 2nd Annual Report of the IVF Registry. Once again, it has been coordinated by the American Fertility Society and Medical Research International. It is a major endeavor undertaken by the Society of Assisted Reproductive Technologies.

The 1987 report indicates tremendous growth in the field in regard to number of patients treated. In 1986, the report was based on 2864 cycles, whereas in 1987, 14,647 cycles are analyzed. The clinical pregnancy rate for IVF/ET remains the same at 16%, whereas the clinical pregnancy rate for GIFT cycles in 1987 was 25%. A seminal figure is the fact that 90% of clinics reporting have at least the birth of one baby.

Hopefully, this information will be helpful to the medical as well as the patient community.

ALAN H. DECHERNEY, M.D.
President
SART

STATEMENT

OF

WILLIAM MACLEOD, DIRECTOR
BUREAU OF CONSUMER PROTECTION
FEDERAL TRADE COMMISSION

BEFORE THE

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SMALL BUSINESS
SUBCOMMITTEE ON REGULATION AND BUSINESS OPPORTUNITIES

MARCH 9, 1989

Mr. Chairman and Members of the Subcommittee: My name is William MacLeod and I am the Director of the Bureau of Consumer Protection at the Federal Trade Commission. I am happy to have the opportunity to appear before you today to discuss the Commission's involvement in the policing of fraud perpetrated against a most vulnerable group, infertile couples -- and by infertile couples, I mean those that have been trying without success to have children.[1]

The market for infertility treatments is a substantial one. In 1988, the Office of Technology Assessment (OTA) reported that approximately 2.4 million married couples in the U.S. are infertile. The OTA also estimated that infertile couples spent as much as $1 billion during 1987 in an effort to combat infertility.[2]

In addition, the treatments available for infertile couples have increased dramatically in recent years. According to OTA, infertile patients obtain care from an estimated 45,600 physicians: 20,600 obstetricians-gynecologists, 17,500 general family practitioners, 6,100 urologists, and 1,400 surgeons.

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[1] The views expressed in this statement are those of the Bureau of Consumer Protection and do not necessarily reflect the views of the Commission or of any individual Commissioners.

[2] U.S. Congress Office of Technology Assessment, Infertility: Medical and Social Choices, OTA-BA-358 (Washington, D.C.: U.S. Government Printing Office, May, 1988).

Sophisticated and innovative procedures for treating infertility are increasingly available in urban areas and university medical centers. In vitro fertilization ("IVF") and gamete intrafallopian transfer ("GIFT") offered by physicians in university hospital programs and specialized clinics ultimately may provide the last resort for help to couples who might otherwise remain childless.

Because the treatment of infertility generally is practiced by physicians at a local level, consumer protection efforts would ordinarily rest with state medical boards and offices of the state attorneys general. Thus, FTC intervention in this area should be cautious and selective. Nevertheless, as our enforcement experience demonstrates, the Commission can play an important and useful consumer protection role under the general authority provided by Section 5 of the Federal Trade Commission Act.

Section 5 declares acts or practices that are deceptive or unfair to be unlawful. Deception in the sale of infertility services, like other forms of misrepresentation, falls within the parameters set forth in the Commission's Deception Statement.[3] Briefly, the Commission has determined that an act or practice is deceptive if (1) there is a representation, omission or practice that (2) is likely to mislead consumers acting reasonably under the circumstances, and (3) the representation, omission or practice is material.[4]

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[3] The Deception Statement is set forth in a letter from the Commission to the Honorable Robert Packwood, Chairman, Committee on Commerce, Science and Transportation, U.S. Senate, October 14, 1983.

Moreover, the Commission has held that it is an unfair or deceptive practice to make an objective product or service claim unless the advertiser has a reasonable basis for believing the claim to be true at the time it is made.[5] As the Commission's policy statement on ad substantiation makes clear, and consistent with recent court decisions upholding the Commission's authority to require substantiation,[6] the level of substantiation required for any given claim will vary depending on the type of claim made.[7]

The Commission uses six criteria as part of a balancing analysis that enables it to determine what level of substantiation is appropriate for a particular claim. These six factors are:

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[4] See Cliffdale Associates, Inc., 103 F.T.C. 110 (1984).

[5] See, FTC Policy Statement Regarding Advertising Substantiation, 49 Fed. Reg. 30999-31001 (August 2, 1984); Thompson Medical Company, 104 F.T.C. 648, 839-42 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 107 S. Ct. 1289 (1987).

[6] See, e.g., Thompson Medical Co., supra, 791 F.2d at 194-95.

[7] As a general rule, all claims must be supported by the level of substantiation they communicate to the reader or listener. If the advertisement does not expressly or impliedly state a particular level of support for its claims, the Commission looks at whether the advertiser has a "reasonable basis" for the claims.

(1) The type of claim;
(2) The type of product or service;
(3) The benefits of a truthful claim;
(4) The consequences of a false claim;
(5) The cost of developing substantiation for the claim; and
(6) The amount of substantiation experts in the field believe is reasonable.

Under this flexible approach, the required level of substantiation rises with the potential for consumer injury should the claim turn out to be false. For example, where the particular product or service claim raises concerns about possible injury to the health or safety of consumers or will be difficult or impossible for consumers to assess for themselves, the FTC requires a relatively higher level of substantiation.[8]

Let me describe briefly how these principles can apply to specific activities in the field of infertility services. One type of abuse that is especially likely to attract our attention is the misrepresentation of success rates. As the OTA report stated, not only do success rates vary considerably, but they are also reported in various ways. For example, some clinics may claim particular success rates based on national success statistics in this field, even though the clinic itself has been operating for years with success rates far below the national averages. Consumers may well be led by such claims into a mistaken belief that their likelihood of achieving a pregnancy is higher than it is. In other instances, success may be reported in terms of achieving a clinical pregnancy. That rate is significantly more optimistic than the chances of actually taking a baby home, however, because it does not account for subsequent miscarriages or stillbirths. To the extent that infertile couples are misled by claims such as these, they can suffer severe emotional and economic harm.

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[8] See, Thompson Medical Co., supra, 104 F.T.C. at 822.

Other practices of interest to us would be false claims of "guaranteed" success, the use of drugs to trigger false positive pregnancy tests, the falsification of test reports indicating that a woman has achieved a pregnancy, and similar conduct. Our attempts to halt practices such as these should not be construed as any interest in the policing of malpractice or neglect in the provision of medical services. Our interest is limited to deception in the marketing of fertility services to unwary consumers.

I mentioned previously the aggregate cost of infertility treatments to consumers in general. But it is also important to consider the costs imposed upon typical patients individually as a consequence of fraud or deception in this market. IVF AND GIFT programs are expensive, often costing more than $6,000 per attempt; thus, the financial injury sustained by consumers who rely on false claims can be quite significant. Perhaps even more significant, though, are the non-monetary costs of fraud in this market. A failure to achieve conception, particularly if conception was "guaranteed" by the provider, can exact a terrible emotional toll. Indeed, it is even possible that some consumers could be led on by a fraudulent provider for an extended period, foregoing other treatments, to the point at which childbearing is simply no longer possible.

As you know, in January the Commission brought an action in which some of the claims described above are at issue.[9] The Commission has since obtained a preliminary injunction in that case, which continues in litigation. We have been keeping the Subcommittee staff advised of the progress of that case, and will continue to do so. As you will recall, the practices involved in that case came to the attention of this Subcommittee in hearings last spring. Several witnesses appearing before the Subcommittee later provided invaluable assistance to the Commission's effort to develop the case. More generally, this Subcommittee deserves credit for bringing the issue of possible fraud and deception in the infertility area to the attention of the public.

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[9] Federal Trade Commission v. Jacobson et al., Civil Action No. 89-0078-A (filed Jan. 18, 1989, E.D. Va.).

Presently, the Commission staff is assessing the need for additional law enforcement action in this area. As part of this effort, we are continuing to work closely with Subcommittee staff. We are especially interested in obtaining information that would reveal the extent to which false or unsubstantiated statements are being made to consumers, including the extent to which infertile couples and others are being exploited by some physicians' possible misuse of success rates in the offering of IVF and GIFT. Toward that end, we are looking forward to receiving the data recently obtained by the Subcommittee from its survey of over 250 IVF and GIFT clinics.

We intend to remain vigilant against deceptive practices that may exist in this area. It is important to note, however, that the Commission cannot -- and should not -- be the sole guardian against abuses in the infertility area. Because reproductive clinics tend to be relatively small economic units that engage in local marketing or advertising, routine policing by medical boards and consumer protection officials at the state or local level is essential.

For our part, we will continue our active monitoring of health claims, not only in the area of infertility, but in other areas as well. I am encouraged to report that we are not alone in this larger battle against health care fraud. We are in frequent contact with various consumer and professional groups, such as the American Medical Association, that receive complaints and other information regarding the marketing of health care services and fraud in the provision of health care.[10] In the past, our monitoring and coordination with these groups have led to cases dealing with such problems as the marketing of bogus non-surgical face lift procedures and the sale of hair analysis services based on misrepresentations of the ability of hair analysis to help in the diagnosis of health care needs. We believe that continued coordination with these groups, including sources on infertility issues provided to us by the Subcommittee staff, can lead to further progress against health care fraud in the future.

In summary, I would emphasize that we recognize the importance of challenging deceptive practices in this area. This Subcommittee's hearings have demonstrated, and our own investigative experience confirms, that infertile couples can be subjected to substantial economic and psychological injury through fraud and deception in this market. We remain interested in obtaining information regarding the degree to which providers of infertility services may be engaged in deceptive practices, with an eye toward potential additional law enforcement actions. To that end, we will continue to work closely with your staff and others who are concerned about possible fraud and deception in the market for infertility treatments.

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[10] The American Medical Association recently estimated that health fraud constitutes a 10 to 25 billion dollar a year industry in the United States. American Medical Association, Division of Library and Information Management, Alternative Therapies, Unproven Methods, and Health Fraud, A Selected Annotated Bibliography (1988). See also, Select Committee on Aging, Quackery, A $10 Billion Scandal, U.S. House of Representatives, 98th Cong., 2d. Sess. (May 31, 1984).

Thank you for the opportunity to appear before this Subcommittee to discuss the Commission's activities. I would be most pleased to answer any questions.

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high-protein intake. But the panel notes that diets rich in animal protein have no known benefits and may increase the risk of colon or breast cancer. Whether pro-in is the villain is not clear, however, nce meats are typically loaded with fat.

The panel vehemently condemned the use of dietary supplements. Some 40% to 60% of Americans routinely swallow vitamins, mineral tablets, protein powders and the like. Yet most people do not need more than the RDAs for vitamins and minerals, and they get that easily through a varied diet. Megadoses have no benefits and can be toxic.

Similarly, the report says, there is no convincing evidence that calcium supplements help prevent osteoporosis, a crippling bone disease prevalent in older women. The calcium RDA is 800 mg; women now consume about three-quarters of that amount. They could make up the shortfall by drinking a 5-oz. glass of low-fat milk each day.

Fish-oil capsules got a thumbs down too. Eating marine fish one or more times a week is thought to help lower cholesterol, but proof that concentrated fish oil has the same result is lacking, and there is no information on its long-term effects. Nor are fiber supplements warranted as a hedge against cancer of the stomach, large intestine and lungs. Though the panel endorses eating more high-fiber foods, no one knows if the ben-ficial effects result from the fiber itself.

As for alcohol, the report advises those who drink to limit intake to less than 1 oz. daily, the equivalent of two cans of beer or two small glasses of wine. Though some researchers believe moderate drinking may have a protective effect against heart disease, the report finds that the risks of alcohol far outweigh any benefits. Women who are pregnant or trying to conceive should avoid alcohol. The panel also urged the public to limit salt consumption to 6 g—about a teaspoon—or less a day.

How difficult will it be for the U.S. to meet these goals? Americans are now on target for protein. But they still need to raise carbohydrates and lower total fats and saturated fats, salt and alcohol. Men now consume 45% more cholesterol than recommended.

The report stresses that the new guidelines are realistic and feasible, requiring djustments but no real deprivations. Americans may still safely eat meat, pro-ided it is "lean meat in smaller and fewer ortions than is customary." Says Dr. eWitt Goodman, a member of the panel om Columbia University: "The recom-ndations are compatible with gourmet, licious eating." Some Americans may spute that, but they will have to decide hich is more important—good taste or od health. *—By Anastasia Toufexis. ported by Andrea Dorfman/New York and k Thompson/Washington*

Medicine

Trying to Fool the Infertile

Is in-vitro fertilization being oversold?

It was only eleven years ago that Louise Brown became the first baby to start life outside a mother's womb. Since then, the business of in-vitro fertilization—conception in a test tube—has grown even faster than Louise has. Some 200 IVF clinics have sprung up in the U.S., and they have been responsible for more than 5,000 births. The surging demand stems from the high incidence of infertility: about 1 married couple in 12 has not been able to conceive a child despite a year of trying. IVF dangles one last shred of hope before some of these 2.4 million couples.

Technicians freeze sperm and eggs at an IVF lab

Clinics can vary dramatically in their success rates.

But the procedure remains an expensive long shot, which fails perhaps 85% of the time. This week the House Subcommittee on Regulation, Business Opportunities and Energy will hold hearings to investigate growing complaints that many heavily promoted IVF clinics misrepresent their success rates. The panel's chairman, Oregon Democrat Ron Wyden, intends to reveal an industry survey showing that the performance of IVF practitioners varies enormously. According to Wyden, half the IVF clinics have yet to achieve a birth, though they may charge up to $7,000 for each fertilization attempt. Says the Congressman: "With millions of couples, many of them desperate, spending huge sums of money on technology that has been sold through borderline advertising, you've got a prescription for disaster."

The top-rated clinics can honestly boast that up to 17% of their patients become parents as a result of IVF. But some lesser operations apparently cite similar potential success rates in their come-ons, even though their own performance may be far worse. Says Geoffrey Sher, medical director of San Francisco's Pacific Fertility Center: "The consumer is in the dark. A startling number of programs have never had a single baby born, and they are still quoting statistics." Doctors can start up clinics even if they have little experience or specialized training. "It's very easy for the medical profession to take advantage of infertile couples because they so desperately want children," observes Carol Peters, chairman of the Texas-based Advocates for Parenthood, a political-action group.

Some couples are bitter about their experience with IVF. One 29-year-old woman in Dallas underwent several unsuccessful IVF attempts at a total cost of some $17,000. She complains that her doctor never told her that his success rate had dropped from 25% to 5% or that the clinic's new embryologist had never helped produce a birth. Says the woman: "I put trust in people, and that doesn't work. I have this desire so bad for a baby, I would do anything to make it work, and I find out I've been ripped off the whole time."

The industry insists that most customers are not cheated because they are told their chances of having a baby are slim. And many fertility specialists doubt that misleading advertising is as prevalent as Wyden claims. In fact, his assertion that half the clinics have never had a birth may be overstated because at least some of them have not been open long enough for a patient to complete a pregnancy.

But there is no denying Wyden's contention that the industry has "virtually no oversight." He will soon introduce legislation requiring that IVF labs be certified by the Government. In the meantime, Wyden will publish his survey, listing clinics, the qualifications of their personnel and their success rate. The report could become a much needed consumer's guide to IVF. In Wyden's view, if a husband and wife put down $7,000, they have a right to know what chance they have of getting a joyous return on their investment. *—By Michael D. Lemonick. Reported by Dick Thompson/Washington, with other bureaus*

NOTE ON SURVEY RESPONDENTS WHO DO IVF AND/OR GIFT

Attached is a list of all clinics who responded to the IVF/GIFT survey.

Clinics whose names and addresses are indented are satellites of the clinics directly above them. Their data is included with their parent clinic.

There are a number of clinics listed whose data is not reflected in the computer print out. For a variety of different reasons these clinics were not able to provide us with all of the data necessary for computer input. All of the following clinics did respond and each clinic's survey, whether or not complete, will be published in its entirety with the hearing report.

SURVEY RESPONDENTS WHO DO IVF AND/OR GIFT

ALABAMA

Assisted Reproductive Technology Program
508 Brookwood Womens Medical Plaza
2006 Brookwood Medical Center Drive
Birmingham, AL 35209

University of Alabama Birmingham Medical Center
Department of Ob/Gyn
547 Old Hillman Building
University Station
Birmingham, AL 35294

University of South Alabama
IVF/Gift Program: Dept. of Ob/Gyn
Division of Reproductive Endocrinology
Mobile. AL 36688

ARIZONA

Arizona Center for Fertility Studies
IVF-ET Program
4614 East Shea Blvd, D-250
Phoenix, AZ 85028

Arizona Fertitlity Institute
2850 North 24th Street, Suite 500-A
Phoenix, AZ 85008

The Reproductive Institute of Tucson
Building G Suite 7
1200 North El Dorado Place
Tuscon, AZ 85715

Southwest Fertility Center
3125 North 32nd St. Suite 200
Phoenix, AZ 85018

CALIFORNIA

Alta Bates Hospital
In Vitro Fertilization Program
3001 Colby Stree
Berkeley, CA 94705

Central California IVF Program
Fresno Community Hospital
PO Box 1232
Fresno, CA 93715

Infertility, Gynecology & Obstetrics Medical Group
9339 Genesee Avenue, suite 220
San Diego, CA 92121

Scripps Clinic Fertility Center
10666 North Torrey Pines Road
La Jolla, CA 92037

UC Irvine Memorial Hospital
2880 Atlantic Avenue Suite 220
Long Beach, CA 90806

Hospital of Good Samaritan
Institute for Reproductive Medicine
1245 Wilshire Blvd. Suite 905
Los Angeles, CA 90017

UCLA School of Medicine
Department of Ob/Gyn: IVF Program
CHS-22-168
Los Angeles, CA 90024

USC School of Medicine
California Reproductive Health Institute
1338 South Hope Street
Los Angeles, CA 90015

Southern California Fertility Institute
California Institute for IVF
Right to Parenthood Program
12301 Wilshire Blvd. Suite 415
Los Angeles, CA 90025

Cedars-Sinai Hospital
Center for Reproductive Medicine
444 South San Vincinte Blvd. 11th Floor
Los Angeles, CA 90048

Fertility & Reproductive Health Institute of Northern California
2516 Samaritan Drive Suite A
San Jose, CA 95124

Nova Fertility Center
101 S. San Mateo Drive #201
San Mateo, California

Century City Hospital
IVF Program
2070 Century Park East
Los Angeles, CA 90067

AMI-South Bay Hospital
In Vitro Fertilization Center
514 South Prospect Avenue
Redondo Beach, CA 90277

Northridge Hospital Medical Center
IVF Program
18300 Roscoe Blvd.
Northridge, CA 91328

Huntington Reproductive Center
39 Congress Street, suite 202
Pasadena, CA 91105

Northern California Fertility Institute
87 Scripps Drive Suite 202
Sacramento, CA 95825

Forest Fertility Center
2110 Forest Avenue
San Jose, CA 95128

UCSF Fertility Associates
University of California San Francisco
Dept. of Ob/Gyn & Reproductive Sciences
Box 0132 Rm. M-1489
San Francisco, CA 94143

Pacific Fertility Center
2100 Webster Street, suite 220
San Francisco, CA 94115

Reproductive Endocrinology & Infertility Clinic
Stanford University
Dept. of Ob/Gyn
S-385 Medical Center
Stanford, CA 94305

John Muir Memorial Hospital
Dept. of Ob/Gyn: IVF Program
1601 Ygnacio Valley Road
Walnut Creek, CA 94598

Whittier Hospital Medical Center
The Genesis Program for IVF
Center Human Development
15151 Janine Drive
Whittier, CA 90605

Hoag Fertility Services
Hoag Memorial Hospital
351 Hospital Road suite 316
Newport, CA 92663

COLORADO

Reproductive Genetics In Vitro
455 South Hudson Street, Level Three
Denver, CO 80222

Conceptions Unlimited
455 S. Hudson Street, Level One

Denver, CO 80222

Infertility, Gynecology & Obstetrics
601 E. Hampden #185
Englewood, CO 80110
CONNECTICUT

Reproductive Endocrinology and Fertility
University of Connecticut Health Center
Department of Ob/Gyn
263 Farmington Avenue
Farmington, CT 06790

Mount Sinai Hospital
Department of Ob/Gyn
Division of Reproductive Endocrinology and Infertility
675 Tower Avenue
Hartford, CT 06112

Yale University Medical School
Department of Ob/Gyn: IVF Program
333 Cedar Street
New Haven, CT 06510

DELAWARE

Reproductive Endocrine and Fertility Center
Medical Center of Delaware
4745 Ogletown-Stanton Road
Newark, Delaware 19718

DISTRICT OF COLUMBIA

Columbia Hospital for Women Medical Center
IVF Program
2425 L Street, NW
Washington, DC 20037

George Washington University Medical Center
Department of Ob/Gyn: IVF Program
2150 Pennsylvania Avenue, NW
Washington, DC 20037

FLORIDA

Fertility Institute of Boca Raton
West Boca Medical Center
21644 State Road 7, Highway 441
Boca Raton, FL 33428

Park Avenue Women's Center
University of Florida Associates
817 NW 56 Terrace, suite C
Gainsville, FL 32605

The Fertility Institute of Northwest Florida, Inc.
Gulf Breeze Hospital, suite 202
Gulf Breeze, FL 32561

Memorial Medical Center of Jacksonville
In Vitro Fertilization Program
3343 University Boulevard South
Jacksonville, FL 32216

Northwest Center for Infertility & Reproductive Endocrinology
5800 Colonial Drive, suite 200
Margate, FL 33063

University of Miami
Department of Ob/Gyn
P.O. Box 016960
Miami, FL 33101

Sand Lake Hospital
(Center for Infertility and Reproductive Medicine, Orlando)
9430 Turkey Lake Road, suite 218
Orlando, FL 32819

Florida Fertility Institute
3451 66th North
St. Petersburg, FL 33710

Humana Womens Hospital
University of South Florida
3030 West Buffalo Avenue
Tampa, FL 33607

GEORGIA

Reproductive Biology Associates
993-D Johnson Ferry Road, suite 330
Atlanta, GA 30342

Augusta Reproductive Biology Associates
University Hospital
810-812 Chafee
Augusta, GA 30904

Medical College of Georgia
Humana Hospital-IVF Section
Augusta, GA 30904

HAWAII

Pacific In Vitro Fertilization Institute
Kapiolani Hospital
1319 Punahou Street, suite 1040
Honolulu, HI 96826

Kauai Medical Group
University of Hawaii
Wilcox Memorial Hospital
Department of Ob/Gyn
3420-B Kuhio Highway
Lihue, HI 96766

ILLINOIS

Northwestern Memorial Hospital
IVF Program
Prentice Womens Hospital
333 East Superior Street, suite 454
Chicago, IL 60611

University of Illinois College of Medicine
Department of Ob/Gyn m/c 808
840 South Wood Street
Chicago, IL 60612

Michael Reese Hospital & Medical Center
IVF-ET Program
31st St. at Lake Shore Drive
Chicago, IL 60616

Mount Sinai Hospital Medical Center
Department of Ob/Gyn: IVF Program
California Avenue at 15th Street
Chicago, IL 60608

IVF Program
Rush Prebyterian-St. Lukes Medical Center
1653 West Congress Parkway
Chicago, IL 60612

The Evanston and Glenbrook Hospitals
IVF Program
2050 Pfingsten Road, suite 350
Glenview, IL 60025

Illinois Masonic Medical Center
IVF Illinois
Fifth Floor, Center Court
836 Wellington
Chicago, IL 60657

The Center for Fertility and Reproductive Medicine
Lutheran General Medical Group
1875 Dempster Street, suite 665
Park Ridge, IL 60068

INDIANA

Indiana University Medical Center
Department of Ob/Gyn-Reproductive Endocrinology
926 West Michigan Street, N-262
Inianapolis, IN 46223

Pregnancy Initiation Center
Humana Womens Hospital
8091 Township Line Road, suite 110
Indianapolis, IN 46260

Center for Reproduction & Transplantation Immunology
Methodist Hospital of Indiana
1701 N. Senate Blvd.
Indianapolis, IN 46202

IOWA

University of Iowa Hospitals and Clinics
Center for Advanced Reproductive Care
Iowa City, IA 52242

KANSAS

University of Kansas College of Health Sciences
Ob/Gyn Foundation
39th and Rainbow Blvd.
Kansas City, KS 66103

University of Kansas School of Medicine: Wichita
Center for Reproductive Medicine
HCA-Wesley Medical Center
Division of Reproductive Endocrinology
2903 East Central
Wichita, KS 67214-4976

Reproductive Resource Center of Greater Kansas City
10600 Quivera, suite 110
Overland Park, Kansas 66215

KENTUCKY

University of Kentucky
Department of Ob/Gyn
800 Rose St.
Kentucky Center for Reproductive Medicine
Lexington, KY 40536

Infertility Program
Norton Hospital
University of Louisville
200 E. Chestnut St.
P.O. Box 35070
Louisville, KY 40202-5070

Fertility Institute
Plunkett & Thompson, M.D.s
40 N. Grand Avenue, suite 302
Ft. Thomas, KY 41075

Louisiana

The Fertility Institute of New Orleans
Humana Womens Hospital
6020 Bullard Avenue
New Orleans, LA 70128

Fertility Center of Louisiana
200 West Esplanade Avenue, suite 210
Kenner, LA 70065

MARYLAND

University of Maryland-Baltimore
Ob/Gyn Associates
419 West Redwood Street, Rm. 500
Baltimore, MD 21201

Women's Hospital Fertility Center: IVF Program
Greater Baltimore Medical Center
6701 North Charles Street
Baltimore, MD 21204

The Johns Hopkins Hospital
Division of Reproductive Endocrinology
600 North Wolfe Street
Baltimore, MD 21205

Montgomery Fertility Institute
10215 Fernwood Road #303-304
Bethesda, MD 20817

Union Memorial Hospital
Center for Reproductive Studies and Infertility
201 East University Parkway
Baltimore, MD 21218

MASSACHUSETTS

Brigham and Womens Hospital
IVF Program
75 Francis Street
Boston, MA 02115

New England Medical Center Hospitals
Department of Ob/Gyn-IVF Clinic
750 Washington Street, Box 36
Boston, MA 02111

Boston IVF
1 Brookline Place, suite 602
Brookline, MA 02146

Beth Israel Hospital
IVF/GIFT Program
330 Brookline Avenue
Boston, MA 02215

Atlanticare Fertility Center
500 Lynnfield Street
Lynn, MA 01904

IVF Australia-Boston
Waltham/Weston Hospital & Medical Center
20 Hope Avenue
Waltham, MA 02254-9116
MICHIGAN

Blodgett Memorial Medical Center
IVF Program
1900 Wealthy Street SE, suite 330
Grand Rapids, MI 49506

Hutzel Hospital
Wayne State University: IVF Program
4707 St. Antoine
Detroit, MI 48201

William Beaumont Hospital
IVF Program
3601 West 13 Mile Road
Royal Oak, MI 48072

SCHI Reproductive Endocrinology
Saginaw General Hospital
1000 Houghton Avenue
Saginaw, MI 48603

University of Michigan Medical Center
Division of Reproductive Endocrinology & Infertility
L2021 Womens Hospital-D2202 MOB Box 0718
Ann Arbor, MI 48109-0718

Oakwood Hospital
Center for Reproductive Medicine
18181 Oakwood Blvd., suite 100G
Dearborn, MI 48124

MINNESOTA

Women's Health Center
University of Minnesota VIP Program
Department of Ob/Gyn
Box 395, Mayo Memorial Building
420 Delaware Street, SE

Minneapolis, MN 55455

MISSISSIPPI

University of Mississippi Medical Center
IVF Program
Department of Ob/ Gyn
2500 N. State Street
Jackson, MS 39216

MISSOURI

Jewish Hospital at Washington University Medical Center
Department of Ob/Gyn
216 South Kingshighway
St. Louis, MO 63110

NEBRASKA

University fo Nebraska Medical Center
Department of Ob/Gyn
42nd and Dewey Avenue
Omaha, NE 68105

Nebraska Methodist Hospital
Department of OB/Gyn
8303 Dodge Street
Omaha, NE 68114

NEVADA

Northern Nevada Fertility Institute
350 West Sixth Street, suite 3AB
Reno, NV 89503

NEW HAMPSHIRE

Dartmouth-Hitchcock Medical Center
2 Maynard Street, clinic 500
Hanover, NH 03756

NEW JERSY

UMDNJ-New Jersy Medical School, Newark
Center for Reproductive Medicine F342
150 Bergen Street
Newark, NJ 07103

UMDNJ-Robert Wood Johnson Medical School
IVF Program: Department of Ob/Gyn
#1 Robert Wood Johnson Place, CN19

New Brunswick, NJ 08903

NEW MEXICO

Presbyterian Hospital
IVF Program
Cedar Street Southeast
Albuquerque, NM 87106

NEW YORK

Children's Hospital of Buffalo
Reproductive Endocrinology Unit
140 Hodge Avenue
Buffalo, NY 14222

Albert Einstein College of Medicine
Fertility and Hormone Center
88 Ashford Avenue
Dobbs Ferry, NY 10522

Cornell University Medical Center
Program for In Vitro Fertilization:
Center for Reproductive Medicine and Infertility
515 East 71st Street, 2nd Floor
New York, NY 10021

Wayne H. Decker IVF Program
1430 Second Avenue, suite 103
New York, NY 10021

Life Program
Albany Memorial Hospital
600 Norhtern Blvd.
Albany, NY 12203

Mount Sinai Medical Center
IVF Program
1212 5th Avenue Box 1175
New York, NY 10029

St. Luke's Roosevelt Hospital Center
IVF-ET Program
1111 Amsterdam Avenue
New York, NY 10025

Columbia-Presbyterian Medical Center
Presbyterian Hospital IVF Program
622 West 168th Street PH-16
New York, NY 10032

IVF Australia at United Hospital
406 Boston Road
Port Chester, NY 10573

Long Island IVF
60 North Country Road
Port Jefferson, NY 11777

University of Rochester Care Program
University of Rochester Medical Center
601 Elmwood Avenue
Rochester, NY 14642

SUNY Health Science Center
Crouse Irving Memorial Hospital
Department of Ob/Gyn
Division of Reproductive Endocrinology
Syracuse, NY 13210

NORTH CAROLINA

UNC Medical School
In Vitro Fertilization-GIFT Program
The North Carolina Memorial Hospital
Department of Ob/Gyn Box 7570
Chapel Hill, NC 27599-7570

Michael Hoffman, MD
7 Pointe Circle
Greenville, SC 29615

Duke University Medical Center
Department of Ob/Gyn Box 3527
Durham, NC 27710

North Carolina Reproductive Center
P.O. Box 4052
1200 N. Elm Street
Greensboro, NC 27404

Women's Specialty Center
Charlotte Memorial Hospital
1901 Brunswick Avenue
Charlotte, NC 28207

OHIO

Akron City Hospital
IVF Program
525 East Market Street
Akron, OH 44309

Riverside Reproductive Services
3726 K Olentangy River Road
Columbus, OH 43214

Jewish Hospital of Cincinnati
Department of Ob/Gyn
3120 Burnet Avenue, suite 204
Cincinnati, OH 45229

University of Cincinnati College of Medicine
Center for Reproductive Health
Bethesda & Eden Avenues (ML456)
Cincinnati, OH 45267

Cleveland Clinic Foundation
IVF Program
9500 Euclid Avenue
Cleveland, OH 44106

Bethesda Fertility Center
619 Oak Street, 3 south
Cincinnati, OH 45206

MacDonald Hospital for Women
2105 Adelbert Road
Cleveland, OH 44106

Mount Sinai Medical Center
Laboratory for In Vitro Fertilization & Embryo Transfer
1 Mount Sinai Drive
Cleveland, OH 44106

Ohio State University
University Reproductive Center
410 W. Tenth
Columbus, OH 43210

Midwest Reproductive Institute
c/o Nichols Vorys, MD
1492 E. Broad St. suite 1203
Columbus, OH 43205

Miami Valley Hospital
Fertility Program
1 Wyoming Street
Dayton, OH 45409

OKLAHOMA

Henry G. Bennett Fertility Institute
3433 NW 56th Street, suite 200
Oklahoma City, OK 73112

Hillcrest Fertility Center
1145 South Utica, suite 1209
Tulsa, OK 74104

OREGON

Oregon Health Sciences University
Reproductive Research & Fertility Program
3181 SW Sam Jackson Park Road L466
Portland, OR 97201

Northwest Fertility Center
Emanuel Hospital
2801 Norht Gantenbain Avenue
Portland, Oregon 97227

PENNSYLVANIA

Fertility Center at St. Lukes Hospital
801 Ostrum Street
Bethlehem, PA 18015

Christian Fertility Institute
241 North 13th Street
Easton, PA 18042

Albert Einstein Medical Center
Department of Ob/Gyn Klein POB-400
York and Tabor Roads
Philadelphia, PA 19141

Hospital of the University of Pennsylvania
Department of Ob/Gyn
3400 Spruce Street, suite 106
Philadelphia, PA 19104

Pittsburg Institute of Reproductive Medicine
5230 Center Avenue
Pittsburg, PA 15232

Endocrine Histology Associates
7447 Old York Road
Melrose Park, PA 19126

Pennsylvania Reproductive Associates of Pennsylvania Hospit
829 Spruce Street
Philadelphia, PA 19107

Women's Clinic LTD
301 South Seventh Avenue, suite 240
West Reading, PA 19611

Program for IVF and Embryo Transfer
Magee Women's Hospital
Department of Ob/Gyn
Pittsburg, PA 15213

RHODE ISLAND

Women's and Infant's Hospital of Rhode Island
161 Dudley Street
Providence, RI 02905

SOUTH CAROLINA

Medical University of South Carolina (MUSC)
Department of Ob/Gyn
171 Ashley Avenue
Charleston, SC 29425

The Southeastern Fertility Center
900 Bowman Road, suite 108
Mount Pleasant, SC 29464

TENNESSEE

East Tennessee State University College of Medicine
Department of Ob/Gyn
Box 19570A
Johnson City, TN 37614

East Tennessee Baptist Hospital
Family Life Center
7A Office 715
Blount Avenue, Box 1788
Knoxville, TN 37901

University of Tennessee Fertility Center
1924 Alcoa Highway, U-27
Knoxville, TN 37920

Vanderbilt University
Center for Fertility and Reproductive Research
IVF Program
D-3200 Medical Center North
Nashville, TN 37232

University of Tennessee-Memphis
Program for Advanced Infertility & Reproduction
66 North Pauline
Memphis, TN 38105

TEXAS

Saint David's Community Hospital
IVF-GIFT Program
1302 West 38th Street
PO Box 4039
Austin, TX 78765

Trinity IVF/ET Program
Trinity Medical Center
4333 North Josey Lane, suite 200
Carrolton, TX 75010

Presbyterian Hospital of Dallas
PO Box 17
Dallas, TX 75231

University of Texas-SW Medical School
Division of Reproductive Endocrinology
Department of Ob/Gyn
Dallas, TX 75235

J.B. Belue, M.D.
120 E. Charnwood
Tyler, TX 75701

Scott & White Clinic
Texas A & M College of Medicine
2401 South 31st Street
Temple, TX 76508

Fort Worth Infertility Center
1325 Pennsylvania Avenue, suite 750
Fort Worth, TX 76104

Texas Fertility Center
HCA Medical Plaza, 4th Floor
1612 West Humbolt
Ft. Worth, TX 76104

University of Texas Medical Branch
IVF Program
Department of Ob/Gyn
Galveston, TX 77550

Baylor College of Medicine
Department of Ob/Gyn
#1 Baylor Medical Plaza
Houston, TX 77054

Ob & Gyn Associates
7550 Fannin
Houston, TX 77054

Houston Reproductive Center
Sam Houston Memorial Hospital
1615 Hilllendahl Boulevard
Houston, TX 77055

University of Texas Health Science Center
Department of Reproductive Science
6431 Fannin, suite 3.204
Houston, TX 77030

Texas Tech University Health Sciences Center
Department of Ob/Gyn
3601 4th Street
Lubbock, TX 79430

Center for Reproductive Medicine
8100 Fredericksberg Road
San Antonio, TX 78229

UTAH

University of Utah
Department of Ob/Gyn
Fertility Center Office
50 Medical Drive Norht
Salt Lake City, UT 84132

VERMONT

University of Vermont College of Medicine
Division of Reproductive Endocrinology
Department of Ob/Gyn
Burlington, VT 05405

VIRGINIA

University of Virginia Health Sciences Center
IVF/GIFT Program
Division of Reproductive Endocrinology
Department of Ob/Gyn
Charlottsville, VA 22908

Jones Institute for Reproductive Medicine
Eastern Virginia Medical School
Hofheimer Hall, Sixth Floor
825 Fairfax Avenue
Norfolk, VA 23507

Medical College of Virginia
IVF Program
Box 34, MCV Station
Richmond, VA 23298

Henrico Doctors Hospital
Richmond Center for Fertility and Endocrinology
7605 Forest Avenue, suite 207
Richmond, VA 23229

WASHINGTON

Swedish Hospital Medical Center
Reproductive Genetics Laboratory
747 Summit Avenue
Seattle, WA 98104

University of Washington
Special Fertlility Programs
Department of Ob/Gyn RH20
University Hospital
Seattle, WA 98195

Rice and Associates
West 104 Fifth Avenue, Room 410
Spokane, WA 99204

Fertility Clinic of Puget Sound
South 36th and Pacific Avenue
Tacoma, WA 98408

Seattle Fertility & Gynecology
1229 Madison, suite 1220
Seattle, WA 98104

Seattle Women's Clinic
IVF Program
801 Broadway, suite 511
Seattle, WA 98112

WEST VIRGINIA

West Virginia University
Department of Ob/Gyn
830 Pennsylvania Avenue
Charleston, WV 25302

WISCONSON

Appleton Medical Center
Family Fertility Program
1818 Meade Street
Appletone, WI 54911

University of Wisconson Clinics
Madison Infertility Clinic
600 Highland Avenue
H4/630 CSC
Madison, WI 53792

Waukesha Memorial Hospital
IVF Program
725 American Avenue
Waukesha, WI 53186

Advanced Institute of Fertility
2000 West Kilbourn Avenue, suite 462
Milwaukee, WI 53233

NONRESPONDENTS TO IVF/GIFT SURVEY

University of Arkansas Medical Sciences
4301 W. Markham slot 518
Little Rock, 72205

Bruce McLucas, MD
2428 Santa Monica Blvd
Santa Monica, CA 90404

Robert Adams, MD
966 Cass Street, suite 200
Monterey, CA 93940

University of California-Irvine
C/O 12555 Garden Grove Blvd, suite 203
Garden Grove, CA 92643

Thomas Watts, MD
Family Fertility Center
730 Potomac Street, suite B4
Aurora, CO 80011

Donald Ketterhagen, MD
Naples Life Program
775 First Avenue North
Naples, Florida 33940

Singh & Raj MDs
Louisiana State Medical Center
1542 Tulane Avenue
New Orleans, LA 70112

Boston University Medical Center
720 Harrison Avenue, suite 501
Boston, MA 02118

Greater Boston In Vitro Associates
Newton-Wellesly Hospital
2000 Washington Street, suite 342
Newton, MA 02162

A. Afsari, MD
7419 Middle Belt, suite 1
W. Bloomfield, MI 48033

Rochester Methodist Hospital
201 West Center Street
Rochester, MN 55902

St. Johns Mercy Medical Center
621 Ballas Road, suite 2009
St. Louis, MO 63141

Truman Medical Center
Department of Ob/Gyn
2301 Holmes
Kansas City, MO 64108

St. Lukes Hospital
4400 Broadway, suite 309
Kansas City, MO 64111

Silber & Cohen
224 South Woods Mill Road, suite 730
St. Louis, MO 63107

Cooper Hospital/University Medical Center
Department of Ob/Gyn: IVF Program
Camden, NJ 08103

West Side Fertility Center
Brandeis Fertility Institute
100 West 89th Street
New York, NY 10024

Chapel Hill Fertility Services
109 Conner Drive, suite 2104
Chapel Hill, NC 27514

Center for Reproductive Medicine
2034 Randolph Road
Charlotte, NC 28207

Sheldon Schlaff, MD
Pennsylvania Endocrine Laboratory
330 S. 9th Street
Philidelphia, PA 19107

Rosewood Medical Center
9200 Westheimer Road
Houston, TX 77063

Memorial Reproductive Services
7600 Beachnut
Houston, TX 77074

Memorial Care Systems
7777 SW Freeway, suite 200
Houston, TX 77459

Genetics and IVF Institute
Fairfax Hospital
3020 Javier Road
Fairfax, VA 22031

SURVEY RESPONDENTS WHO DO NOT PRESENTLY DO IVF AND/OR GIFT

Barry L. Wilson, MD & Dent Williams, MD
2055 East South Boulevard, suite 308
Montgomery, AL 36106

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MINORITY SUBCOMMITTEE PROFESSIONAL
STAFF MEMBER
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Polled 224 Responded 192 Elligible 165 Included 146 No IVF/GIFT 24

Statistics for total IVF/GIFT Survey

Women 24195 Births 4220 Adj. Births 3545 Stim. Cyc. 34404 Succ Rate 10%

1987 & 1988 totals by method

IVF

Women 18573 Births 2949 Adj. Births 2489 Stim. Cyc. 26723 Succ Rate 9%

GIFT

Women 5622 Births 1271 Adj. Births 1056 Stim. Cyc. 7681 Succ Rate 14%

yearly totals by method

IVF 87

Women 8288 Births 1109 Adj. Births N/A Stim. Cyc. 12104 Succ Rate 9%

IVF 88

Women 10285 Births 1840 Adj. Births 1380 Stim. Cyc. 14619 Succ Rate 9%

GIFT 87

Women 2310 Births 377 Adj. Births N/A Stim. Cyc. 3488 Succ Rate 11%

GIFT 88

Women 3312 Births 894 Adj. Births 679 Stim. Cyc. 4193 Succ Rate 16%

Births -- This number is artificially high. It assumes that all continuing pregnancies from 1988 will result in live births in 1989. The actual number of births for 1988 cannot accurately be determined until August 1989.

Adj. Births -- Continuing pregnancies are adjusted to account for the likely rate of termination. IVF is reduced by .25 and GIFT is reduced by .24, according to the American Fertility Society's Continuing Registry.

CHART I

NAME	STIMULATION CYCLES 87-IVF-88		87-GIFT-88		EGG RECOVERIES 1987	1988	EMBRYO TRANSFER 1987	1988	LIVE BIRTHS 87-IVF-88		87-GIFT-88		CONT. PREGNANCIES 87-IVF-88		87-GIFT-88	
AL-ASSISTED REPRODUCTIVE	268	219	0	0	127	101	190	164	29	29	0	0	0	23	0	1
AL-UNIV. OF AL BIRMINGHAM	52	20	0	30	20	21	20	20	1	0	1	0	0	4	0	4
AL-UNIV. OF S. ALABAMA	17	22	1	1	17	21	14	16	0	0	0	0	0	0	0	0
AZ-ARIZONA FERTILITY INST	81	117	12	1	72	108	64	87	12	4	1	0	0	8	0	0
AZ-REPRO. INST. OF TUCSON	8	10	10	0	7	7	6	10	0	0	2	0	0	1	0	1
AZ-SOUTHWEST FERTILITY	0	6	31	41	0	4	0	3	0	0	3	1	0	1	0	3
CA-ALTA BATES HOSPITAL	137	141	2	2	109	114	106	108	17	13	0	0	0	14	0	0
CA-AMI-SOUTHBAY HOSPITAL	116	147	3	3	99	122	90	120	25	9	1	1	0	20	0	0
CA-CAL-IRVINE IVF/GIFT	239	263	100	246	163	168	152	176	27	4	20	10	0	26	0	30
CA-CEDARS-SINAI MED CENTR	0	136	0	122	0	90	0	87	0	6	0	19	0	8	0	3
CA-CENTRAL CA IVF PROGRAM	60	90	18	36	64	66	29	71	6	3	2	2	0	10	0	0
CA-CENTURY CITY HOSPITAL	69	106	47	146	69	152	60	107	3	11	0	16	0	18	0	17
CA-FERT & REPRO. HEALTH	0	13	0	1	0	13	0	10	0	0	0	0	0	5	0	0
CA-FORREST FERTILITY CENT.	0	9	0	1	0	9	0	1	0	0	0	0	0	1	0	0
CA-HOAG FERTILITY SERVICE	12	62	0	21	4	39	4	32	0	3	0	0	0	0	0	3
CA-HOSPITAL OF GOOD SAM.	403	200	417	280	204	149	207	136	31	0	42	0	0	19	0	26
CA-JOHN MUIR MEMORIAL	718	390	22	14	365	300	310	254	64	16	3	1	0	47	0	1
CA-NORTH. CALIF. FERT.	76	42	0	25	46	30	41	26	6	0	0	1	0	4	0	3
CA-NORTHRIDGE HOSPITAL	287	168	14	32	160	102	149	129	24	26	0	1	0	12	0	3
CA-NOVA FERTILITY CENTER	5	80	4	19	5	54	4	51	0	4	0	2	1	12	0	3
CA-PACIFIC FERTILITY CENT	0	123	0	0	0	102	0	96	0	6	0	0	0	16	0	0
CA-S. CAL. FERTILITY INS.	30	17	16	23	17	12	14	12	0	1	0	3	0	2	3	3
CA-UCLA MEDICAL CENTER	152	106	3	0	122	98	110	90	22	0	0	0	0	8	0	0
CA-UCSF FERTILITY ASSOC.	194	215	6	4	184	143	100	124	11	6	1	0	0	20	0	2
CA-WHITTIER HOSPITAL	0	13	0	5	0	8	0	7	0	0	0	0	0	1	0	2
CO-REPRODUCTIVE GENETICS	172	264	0	0	120	200	130	170	13	10	0	0	0	17	0	0
CT-MT. SINAI HOSPITAL	45	47	5	7	20	30	22	25	2	1	0	0	0	3	0	0
CT-UCONN SCHOOL OF MED.	47	88	8	7	34	47	33	34	3	3	1	0	0	3	0	0
CT-YALE SCHOOL OF MED.	473	486	40	28	381	342	386	206	22	23	1	1	0	14	0	1
DC-COLUMBIA HOS FOR WOMEN	0	132	0	6	0	124	0	117	0	4	0	0	0	16	0	0
DC-GW UNIVERSITY IVF	12	61	10	14	11	60	7	44	1	1	2	0	0	3	0	0
FL-FERT CEN OF BOCA RATON	4	35	0	10	2	31	2	28	0	1	0	0	0	3	0	0
FL-FLORIDA FERTILITY	10	20	22	23	16	12	10	10	0	0	0	7	0	0	0	5
FL-HUMANA WOMEN'S HOSPIT.	63	89	2	26	44	69	34	43	0	6	0	1	0	6	0	0
FL-JACKSONVILLE MEM MED	19	14	22	20	15	9	12	9	1	1	1	5	0	1	0	1
FL-N.W. FLA. GULF BREEZE	14	26	15	37	12	31	12	29	0	2	0	3	0	4	0	0
FL-NW CENTER FOR INFERT.	28	106	13	16	20	70	11	63	0	3	0	3	3	6	2	0
FL-PARK AVE. WOMENS CENTR	0	7	0	1	0	0	0	6	0	0	0	0	0	7	0	0
FL-SAND LAKE IVF CENTER	89	143	2	8	74	116	62	100	10	9	0	0	0	11	0	1
GA-AUGUSTA REPROD. BIO.	25	30	0	0	24	32	16	21	1	5	0	0	4	7	0	0
GA-MEDICAL COLLEGE OF GA	25	26	1	4	14	19	11	18	3	0	0	0	0	1	0	0
GA-REPRODUCTIVE BIOLOGY	234	329	40	30	156	227	146	176	20	11	2	3	0	46	0	3
HI-KAUAI MEDICAL GROUP	0	5	0	5	0	5	0	5	0	0	0	0	0	0	0	0
HI-PACIFIC IVF INSTITUTE	37	106	0	0	27	88	20	62	5	10	0	0	0	8	0	0
IA-UNIVERSITY IOWA	22	68	5	44	17	62	14	59	0	0	0	2	0	10	0	10
IL-EVANSTON AND GLENBROOK	0	110	0	0	0	100	0	90	0	5	0	0	0	15	0	13
IL-MASONIC MEDICAL CENTER	66	117	21	62	61	90	60	79	2	4	0	6	0	9	0	5
IL-MICHAEL REESE HOSPITAL	108	128	6	66	109	132	97	112	4	1	1	4	0	6	0	4
IL-NORTHWESTERN MEMORIAL	36	16	28	49	27	11	24	11	0	4	0	13	0	1	0	0
IL-RUSH PRESB-ST. LUKE'S	77	73	19	76	77	72	62	64	7	2	0	7	0	8	0	6
IL-U. OF ILLINOIS MED. C.	14	7	3	2	0	4	5	3	0	0	0	0	0	0	0	0
IN-CENTER FOR REPROD.	22	37	6	2	12	26	10	30	0	0	0	0	0	2	0	0
IN-INDIANA UNIVERSITY	1	3	1	37	0	2	0	2	0	0	0	1	0	0	0	0
IN-PREGNANCY INITIATION	201	210	232	358	165	161	146	145	12	0	30	63	0	11	0	65
KS-REPROD. RESOUCE CENTER	89	121	69	94	66	97	66	82	1	12	3	10	0	11	0	10
KS-UNIV. KANSAS WICHITA	24	22	34	25	10	14	13	13	0	1	4	2	0	5	0	2
KY-FERTILITY INSTITUTE	10	1	46	38	10	1	10	1	0	0	0	5	0	0	0	2
KY-NORTON HOSPITAL	57	66	1	1	40	63	43	60	4	0	1	0	0	0	1	0
KY-UNIVERSITY OF KENTUCKY	46	79	60	19	26	59	24	52	2	2	6	2	0	4	0	1
LA-FERT INST NEW ORLEANS	166	78	288	229	90	67	81	48	20	4	26	30	0	10	0	30

MA-ALTANTICARE FERTILITY	0	103	0	0	0	94	0	60	0	1	0	0	0	0	0	0
MA-BRIGHAM & WOMEN'S HOS.	94	121	9	9	65	73	55	55	1	14	1	0	0	5	0	1
MA-NEW ENGLAND MED. CTR.	0	17	0	1	0	16	0	15	0	0	0	0	0	2	0	0
MD-UNIVERSITY OF MARYLAND	0	3	0	1	0	3	0	1	0	0	0	0	0	0	0	0
MD-WOMEN'S HOSPITAL CENTR	440	384	33	36	440	384	288	320	61	34	3	1	0	40	0	6
MI-BLODGETT MEMORIAL IVF	42	51	0	5	29	44	26	40	0	8	0	0	0	5	0	1
MI-HUTZEL HOSP./WAYNE ST.	162	112	1	1	124	92	96	67	11	2	0	0	0	4	0	0
MI-OAKWOOD HOSPITAL	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0
MI-SOMI REPROD. ENDO.	49	70	46	131	41	74	41	73	4	8	10	12	0	10	0	33
MI-UNIV MI MEDICAL CENTER	75	83	2	4	60	61	60	67	3	2	0	0	0	3	0	0
MI-WILLIAM BEAUMONT HOSP.	115	153	2	6	109	110	80	106	10	2	1	0	0	7	0	1
MN-U. OF MINNESOTA	72	139	5	1	52	102	43	83	9	3	0	0	0	10	0	1
MO-WASHINGTON U. JEWISH	77	97	2	2	53	65	43	42	5	4	0	0	0	2	0	0
MS-U. MISS MEDICAL CENTER	66	65	2	4	53	48	46	38	13	2	1	0	0	6	0	0
NC-DUKE UNIVERSITY MED.	71	75	10	11	56	92	46	48	4	1	1	1	0	5	0	0
NC-NC MEMORIAL HOSPITAL	195	0	25	0	127	0	104	0	15	0	1	0	11	0	1	0
NC-NC REPROD. CENTER	6	8	0	0	6	6	0	4	1	0	0	0	0	2	0	0
NE-METHODIST HOSPITAL	10	10	41	1	11	17	0	17	0	0	0	0	0	2	0	0
NE-UNIVERSITY OF NEBRASKA	0	60	0	4	0	40	0	26	0	1	0	1	0	1	0	1
NH-DARTMOUTH-HITCHCOCK	12	10	0	0	0	0	4	5	1	1	0	0	0	1	0	0
NJ-ROBERT WOOD JOHNSON	130	220	0	12	76	101	61	86	5	11	0	0	0	2	0	0
NJ-UMDNJ NJ MED SCHOOL	162	104	1	1	126	156	123	141	13	0	0	0	0	14	0	1
NM-PRESBYTERIAN IVF	0	34	0	17	0	29	0	27	0	1	0	4	0	4	0	2
NY-NORTHERN NY FERTILITY	169	156	5	3	129	123	128	116	17	8	0	0	0	14	0	0
NY-ALBERT EINSTEIN COLL	67	67	45	42	47	55	32	40	2	0	11	1	2	6	11	0
NY-AUSTRALIA,UNITED HOSP.	806	957	0	0	800	907	613	753	107	30	0	0	0	180	0	0
NY-CHILDREN'S HOS. (BUFF)	0	30	0	12	0	22	0	20	0	0	0	0	0	0	0	0
NY-COLUMBIA PRESBYTERIAN	69	71	0	0	66	64	62	63	0	0	0	0	0	4	0	0
NY-LIFE PROGRAM	0	15	0	1	0	15	0	12	0	0	0	0	0	0	0	0
NY-MT. SINAI HOSPITAL	261	311	18	72	193	330	180	304	21	0	4	7	0	21	0	12
NY-NY HOSPITAL-CORNELL	179	213	20	31	110	244	107	211	13	2	4	3	0	34	0	2
NY-ST. LUKE'S ROOSEVELT	36	23	1	2	22	20	17	16	2	0	0	0	2	0	0	0
NY-U. OF ROCHESTER CARE	72	63	2	3	61	60	51	60	3	1	0	0	0	4	0	0
NY-WAYNE DECKER IVF PROGM	16	53	0	0	11	37	9	32	0	1	0	0	0	4	0	0
OH-AKRON CITY HOSPITAL	70	90	1	1	44	68	28	42	2	10	0	0	1	10	0	0
OH-BETHESDA FERTILITY	7	48	16	31	6	41	6	36	1	0	2	1	0	5	0	2
OH-CLEVELAND CLINIC FOUND	179	141	2	0	140	112	110	97	11	10	1	0	0	6	0	0
OH-JEWISH HOSP. OF CIN.	7	5	18	15	3	5	3	5	0	0	0	0	0	1	0	0
OH-MACDONALD HOSP.	44	90	0	0	22	60	10	40	2	0	0	0	0	0	0	0
OH-MIAMI VALLEY HOSPITAL	100	45	13	54	60	41	60	27	5	2	3	5	0	3	0	0
OH-MIDWEST REPROD. INST.	37	43	47	61	26	27	16	36	0	0	3	3	0	3	0	0
OH-MT. SINAI MED. CENTER	71	59	46	20	49	48	42	43	4	2	5	1	0	4	0	3
OH-RIVERSIDE REPROD. SERV	12	51	16	168	10	26	0	31	0	1	0	3	0	1	0	0
OH-UNIV REPROD. CENTER	105	126	47	81	79	102	66	73	0	4	1	4	2	2	0	1
OK-HENRY BENNETT FERTILTY	24	21	45	34	22	19	16	13	3	1	2	0	0	0	0	0
OK-HILLCREST FERTILITY	46	62	0	0	40	60	20	40	2	0	0	0	0	7	0	0
OR-EMANUEL HOSPITAL	29	66	2	2	27	54	25	60	4	2	0	0	0	4	0	0
OR-OR HEALTH SCIENCE UNIV	77	63	32	20	40	63	48	42	3	3	2	3	0	0	0	0
PA-ALBERT EINSTEIN MED	46	67	2	1	26	67	27	46	0	3	0	0	0	3	0	0
PA-[illegible] HOSP. ASSOC.	0	211	0	0	0	200	0	155	0	1	0	0	0	10	0	0
PA-FERT. CTR. ST. LUKES	0	10	0	79	0	0	0	0	0	0	2	0	0	0	0	0
PA-HOSPITAL OF U. PENN.	320	310	10	55	188	284	181	233	15	14	0	3	0	24	0	1
PA-MAGEE-WOMEN'S HOSPITAL	80	130	63	100	80	160	26	75	0	3	0	0	0	12	0	21
PA-PENN. REPRO. ASSOC.	344	479	100	100	281	393	221	280	31	15	23	0	0	33	0	33
PA-PITTSBURGH INSTITUTE	8	12	0	0	8	10	3	0	0	0	0	0	0	3	0	0
PA-WOMEN'S CLINIC LTD.	45	60	0	0	36	60	31	36	5	2	0	0	0	4	0	0
RI-WOMENS & INFANTS HOSP.	9	14	0	0	9	13	0	11	0	0	0	0	0	3	0	0
SC-MUSC IVF PROGRAM	16	13	0	0	11	11	0	10	0	0	0	0	1	1	0	0
SC-SOUTHEASTERN FERTILITY	56	62	13	73	27	41	23	23	1	1	2	1	0	1	0	11
TN-FAIR (MEMPHIS)	0	14	3	0	0	12	0	11	0	0	0	0	0	0	0	1
TN-VANDERBILT MED CTR.	157	188	33	16	90	110	70	100	11	15	1	4	0	12	0	3
TX-CENTER FOR REPRO. MED.	40	63	26	10	34	60	30	34	5	5	0	3	0	3	1	1
TX-FT. WORTH INFERT. CTR.	66	66	5	7	31	37	30	28	3	1	0	1	0	1	0	1
TX-HOUSTON REPRODUCTIVE	3	31	4	1	6	18	1	3	0	0	0	0	0	4	0	0
TX-J.D. SELMS, M.D.	0	0	20	12	0	0	0	0	0	0	2	1	0	0	0	0
TX-OB & GYN ASSOCIATES	103	190	125	104	80	170	90	146	14	15	40	7	0	30	0	0

TX-PRESB. HOSPITAL DALLAS	0	3	50	49	2	2	3	2	0	0	11	2	0	0	0	0
TX-SCOTT & WHITE CLINIC	0	4	0	3	0	3	0	3	0	0	0	0	0	1	0	1
TX-TRINITY IVF-ET PROGRAM	58	123	4	11	60	107	48	83	10	7	0	3	0	7	0	1
TX-U OF TEX-SW MED SCHOOL	14	30	7	2	11	28	11	18	0	0	0	0	0	0	0	0
TX-UNIV. OF TX GALVESTON	16	0	3	13	15	0	16	0	3	0	1	2	0	0	0	1
UT-UNIVERSITY OF UTAH	96	104	16	9	79	72	85	13	12	9	4	2	0	15	0	1
VA-HENRICO DRS HOSPITAL	31	26	12	17	14	30	13	20	5	4	2	1	0	4	0	4
VA-JONES INSTITUTE	737	782	1	2	637	766	673	628	106	31	0	0	0	80	0	1
VA-MEDICAL COLLEGE OF VA	43	33	0	1	26	20	24	20	1	10	0	0	0	0	0	0
VA-UNIVERSITY OF VIRGINIA	8	3	4	10	8	3	0	3	0	0	0	0	0	1	0	2
VT-UNIVERSITY OF VERMONT	12	7	1	0	7	6	9	6	0	0	0	0	0	0	0	0
WA-FERT CLIN PUGET SOUND	46	17	111	20	20	17	20	16	4	0	0	0	0	1	0	0
WA-RICE & ASSOCIATES	0	1	0	3	0	0	3	0	0	0	0	0	0	0	0	2
WA-SEATTLE FERT & GYN	81	120	141	67	64	98	64	64	0	7	27	10	0	12	0	11
WA-SEATTLE WOMEN'S CLINIC	4	1	0	6	3	1	3	1	0	0	1	1	0	0	0	0
WA-SWEDISH HOSP. MED. CTR	108	148	304	101	90	112	60	88	0	9	34	13	0	12	0	14
WA-UNIV. OF WASHINGTON	175	196	10	0	134	150	122	122	10	10	0	3	0	12	0	2
WI-APPLETON FAMILY FERT.	11	0	1	12	11	0	7	6	1	0	0	1	0	0	0	2
WI-UNIV. OF WISCONSIN	60	76	0	1	21	28	20	26	2	2	0	0	0	1	0	0
WV-W.VIRGINIA UNIVERSITY	0	20	0	80	0	10	0	14	0	0	0	5	0	1	0	4
TOTALS	12104	14010	2680	4100'	9100	11080	8014	10126	1078	000	350	260	34	1231	21	654
AVERAGES	100.0	102.23	3.60	30.01	75.00	88.00	66.02	71.88	8.88	4.20	2.46	2.90	0.28	8.61	0.80	4.31

- Stimulation Cycles : an attempt to produce eggs in a woman.
- Egg Recoveries : the removal of eggs from a woman in order to fertilize them outside of her body.
- Embryo Transfer : the transfer of an egg that has been fertilized outside of a woman s body
  back into her body.
- Live Births: number of live births.
- Continuing Pregnancies : pregnancies that are ongoing but have not yet resulted in a live birth.

CHART II

1987 IVF DATA

NAME	Year	Patients	Stim Cyc	Egg Rec	Live	Cont Preg	L/ER	C/ER	L+C/ER	L+C/SC
AL-ASSISTED REPRODUCTIVE	2.2	185	268	227	29	0	0.13	0.00	0.13	0.11
AL-UNIV. OF AL BIRMINGHAM	6.0	39	53	30	1	0	0.03	0.00	0.03	0.02
AL-UNIV. OF S. ALABAMA	1.6	14	17	17	0	0	0.00	0.00	0.00	0.00
AZ-ARIZONA FERTILITY INST	6.0	68	81	72	12	0	0.17	0.00	0.17	0.15
AZ-REPRO. INST. OF TUCSON	3.0	7	8	7	0	0	0.00	0.00	0.00	0.00
AZ-SOUTHWEST FERTILITY	0.5	0	0	0	0	0	-	-	-	-
CA-ALTA BATES HOSPITAL	6.0	113	137	106	17	0	0.16	0.00	0.16	0.12
CA-AMI-SOUTHBAY HOSPITAL	2.0	91	116	99	26	0	0.26	0.00	0.26	0.22
CA-CAL-IRVINE IVF/GIFT	2.5	197	238	163	27	0	0.17	0.00	0.17	0.11
CA-CEDARS-SINAI MED CENTR	2.4	0	0	0	0	0	-	-	-	-
CA-CENTRAL CA IVF PROGRAM	4.0	56	60	54	6	0	0.11	0.00	0.11	0.10
CA-CENTURY CITY HOSPITAL	6.0	73	88	88	2	0	0.02	0.00	0.02	0.02
CA-FERT & REPRO. HEALTH	0.3	0	0	0	0	0	-	-	-	-
CA-FOREST FERTILITY CENT.	1.0	0	0	6	0	0	0.00	0.00	0.00	-
CA-HOAG FERTILITY SERVICE	1.2	11	12	4	0	0	0.00	0.00	0.00	0.00
CA-HOSPITAL OF GOOD SAM.	6.0	0	402	304	31	0	0.10	0.00	0.10	0.08
CA-JOHN MUIR MEMORIAL	4,7	233	718	365	64	0	0.18	0.00	0.18	0.09
CA-NORTH. CALIF. FERT.	6.0	46	76	46	5	0	0.11	0.00	0.11	0.07
CA-NORTHRIDGE HOSPITAL	4.5	116	257	188	24	0	0.13	0.00	0.13	0.09
CA-NOVA FERTILITY CENTER	1.2	5	5	5	0	1	0.00	0.20	0.20	0.20
CA-PACIFIC FERTILITY CENT	1.0	0	0	0	0	0	-	-	-	-
CA-S. CAL. FERTILITY INS.	4.0	17	20	17	0	0	0.00	0.00	0.00	0.00
CA-UCLA MEDICAL CENTER	5.3	134	162	122	22	0	0.18	0.00	0.18	0.14
CA-UCSF FERTILITY ASSOC.	6.0	140	194	124	11	0	0.09	0.00	0.09	0.06
CA-WHITTIER HOSPITAL	1.0	0	0	0	0	0	-	-	-	-
CO-REPRODUCTIVE GENETICS	6.3	121	173	130	13	0	0.10	0.00	0.10	0.08
CT-MT. SINAI HOSPITAL	4.6	45	46	26	2	0	0.08	0.00	0.08	0.04
CT-UCONN SCHOOL OF MED.	6.0	30	67	34	2	0	0.06	0.00	0.06	0.03
CT-YALE SCHOOL OF MED.	6.6	279	473	331	32	0	0.09	0.00	0.09	0.07
DC-COLUMBIA HOS FOR WOMEN	2.0	0	0	0	0	0	-	-	-	-
DC-GW UNIVERSITY IVF	6.0	12	12	11	1	0	0.09	0.00	0.09	0.08
FL-FERT CEN OF BOCA RATON	1.1	2	4	2	0	0	0.00	0.00	0.00	0.00
FL-FLORIDA FERTILITY	1.2	14	18	16	0	0	0.00	0.00	0.00	0.00
FL-HUMANA WOMEN'S HOSPIT.	3.0	62	62	44	6	0	0.14	0.00	0.14	0.10
FL-JACKSONVILLE MEM MED	2.6	16	19	15	1	0	0.07	0.00	0.07	0.05
FL-N.W. FLA. GULF BREEZE	1.3	16	14	13	0	0	0.00	0.00	0.00	0.00
FL-NW CENTER FOR INFERT.	1.4	24	28	20	0	3	0.00	0.15	0.15	0.11
FL-PARK AVE. WOMENS CENTR	0.2	0	0	0	0	0	-	-	-	-
FL-SAND LAKE IVF CENTER	2.2	75	88	74	10	0	0.14	0.00	0.14	0.11
GA-AUGUSTA REPROD. BIO.	6.0	84	25	24	1	4	0.04	0.17	0.21	0.20
GA-MEDICAL COLLEGE OF GA	6.0	19	25	14	3	0	0.21	0.00	0.21	0.12
GA-REPRODUCTIVE BIOLOGY	6.0	224	224	156	29	0	0.19	0.00	0.19	0.13
HI-KAUAI MEDICAL GROUP	4.0	0	0	0	0	0	-	-	-	-
HI-PACIFIC IVF INSTITUTE	3.6	34	37	27	5	0	0.19	0.00	0.19	0.14
IA-UNIVERSITY IOWA	1.4	16	22	17	0	0	0.00	0.00	0.00	0.00
IL-EVANSTON AND GLENBROOK	2.0	0	0	0	0	0	-	-	-	-
IL-MASONIC MEDICAL CENTER	2.1	47	86	61	2	0	0.03	0.00	0.03	0.02
IL-MICHAEL REESE HOSPITAL	6.0	91	108	100	4	0	0.04	0.00	0.04	0.04
IL-NORTHWESTERN MEMORIAL	2.0	30	35	27	0	0	0.00	0.00	0.00	0.00
IL-RUSH PRESB-ST. LUKE'S	5.1	77	77	77	7	0	0.09	0.00	0.09	0.09
IL-U. OF ILLINOIS MED. C.	4.2	7	14	9	0	0	0.00	0.00	0.00	0.00
IN-CENTER FOR REPROD.	1.2	12	22	12	0	0	0.00	0.00	0.00	0.00
IN-INDIANA UNIVERSITY	6.0	1	1	0	0	0	-	-	-	0.00
IN-PREGNANCY INITIATION	3.0	143	201	152	12	0	0.08	0.00	0.08	0.06
KS-REPROD. RESOUCE CENTER	1.3	57	89	68	1	0	0.01	0.00	0.01	0.01
KS-UNIV. KANSAS WICHITA	1.6	17	24	16	0	0	0.00	0.00	0.00	0.00
KY-FERTILITY INSTITUTE	2.1	10	10	10	0	0	0.00	0.00	0.00	0.00
KY-NORTON HOSPITAL	6.0	44	57	49	4	8	0.08	0.16	0.24	0.21

KY-UNIVERSITY OF KENTUCKY	4.8	33	46	38	2	0	0.05	0.00	0.05	0.04
LA-FERT INST NEW ORLEANS	6.0	131	166	98	20	0	0.20	0.00	0.20	0.12
MA-ALTANTICARE FERTILITY	0.7	0	0	0	0	0	-	-	-	-
MA-BRIGHAM & WOMEN'S HOS.	6.0	61	84	65	2	0	0.03	0.00	0.03	0.02
MA-NEW ENGLAND MED. CTR.	1.9	0	0	0	0	0	-	-	-	-
MD-UNIVERSITY OF MARYLAND	0.3	0	0	0	0	0	-	-	-	-
MD-WOMEN'S HOSPITAL CENTR	4.3	280	440	440	61	0	0.14	0.00	0.14	0.14
MI-BLODGETT MEMORIAL IVF	5.4	37	43	39	8	0	0.21	0.00	0.21	0.19
MI-HUTZEL HOSP./WAYNE ST.	5.5	128	163	124	11	0	0.09	0.00	0.09	0.07
MI-OAKWOOD HOSPITAL	0.1	0	0	0	0	0	-	-	-	-
MI-SCHI REPROD. ENDO.	1.6	38	49	41	4	0	0.10	0.00	0.10	0.08
MI-UNIV MI MEDICAL CENTER	5.0	49	76	60	3	0	0.05	0.00	0.05	0.04
MI-WILLIAM BEAUMONT HOSP.	6.5	95	116	100	10	0	0.10	0.00	0.10	0.09
MN-U. OF MINNESOTA	6.0	63	73	52	9	0	0.17	0.00	0.17	0.13
MO-WASHINGTON U. JEWISH	6.0	61	77	53	5	0	0.09	0.00	0.09	0.06
MS-U. MISS MEDICAL CENTER	5.0	48	86	53	12	0	0.23	0.00	0.23	0.14
NC-DUKE UNIVERSITY MED.	6.0	56	71	50	4	0	0.08	0.00	0.08	0.06
NC-NC MEMORIAL HOSPITAL	6.0	120	196	127	16	12	0.12	0.00	0.21	0.14
NC-NC REPROD. CENTER	1.7	6	6	6	1	0	0.17	0.00	0.17	0.17
NE-METHODIST HOSPITAL	1.6	7	10	11	0	0	0.00	0.00	0.00	0.00
NE-UNIVERSITY OF NEBRASKA	1.0	6	5	0	5	0	-	-	-	-
NH-DARTMOUTH-HITCHCOCK	3.0	10	12	2	1	0	0.11	0.00	0.11	0.08
NJ-ROBERT WOOD JOHNSON	5.5	58	130	76	5	0	0.07	0.00	0.07	0.04
NJ-UMDNJ NJ MED SCHOOL	2.7	106	162	130	13	0	0.09	0.00	0.09	0.08
NM-PRESBYTERIAN IVF	3.0	0	0	0	0	0	-	-	-	-
NY-NORTHERN NY FERTILITY	6.0	142	188	120	17	0	0.12	0.00	0.12	0.09
NY-ALBERT EINSTEIN COLL	2.6	27	67	47	2	2	0.04	0.04	0.09	0.06
NY-AUSTRALIA,UNITED HOSP.	5.7	521	606	650	107	0	0.16	0.00	0.16	0.13
NY-CHILDREN'S HOS. (BUFF)	1.0	0	0	0	0	0	-	-	-	-
NY-COLUMBIA PRESBYTERIAN	5.8	36	60	56	0	0	0.00	0.00	0.00	0.00
NY-LIFE PROGRAM	0.6	0	0	0	0	0	-	-	-	-
NY-MT. SINAI HOSPITAL	2.1	123	261	182	21	0	0.11	0.00	0.11	0.08
NY-NY HOSPITAL-CORNELL	2.0	110	175	116	13	0	0.11	0.00	0.11	0.07
NY-ST. LUKE'S ROOSEVELT	4.0	24	36	22	2	2	0.09	0.09	0.18	0.11
NY-U. OF ROCHESTER CARE	5.5	59	72	61	3	0	0.05	0.00	0.05	0.04
NY-WAYNE DECKER IVF PROGM	1.6	10	16	11	0	0	0.00	0.00	0.00	0.00
OH-AKRON CITY HOSPITAL	3.5	53	70	44	2	1	0.05	0.02	0.07	0.04
OH-BETHESDA FERTILITY	1.5	6	7	5	1	0	0.20	0.00	0.20	0.14
OH-CLEVELAND CLINIC FOUND	4.1	130	176	149	11	0	0.07	0.00	0.07	0.06
OH-JEWISH HOSP. OF CIN.	5.1	6	7	3	0	0	0.00	0.00	0.00	0.00
OH-MACDONALD HOSP.	4.1	261	44	23	2	0	0.09	0.00	0.09	0.05
OH-MIAMI VALLEY HOSPITAL	4.0	98	160	68	5	0	0.07	0.00	0.07	0.03
OH-MIDWEST REPROD. INST.	6.0	31	37	38	0	0	0.00	0.00	0.00	0.00
OH-MT. SINAI MED. CENTER	6.0	45	71	49	4	0	0.08	0.00	0.08	0.06
OH-RIVERSIDE REPROD. ENDV	1.2	11	13	10	0	0	0.00	0.00	0.00	0.00
OH-UNIV REPROD. CENTER	4.3	66	106	78	6	0	0.08	0.00	0.08	0.06
OK-HENRY BENNETT FERTILTY	2.7	17	24	23	3	0	0.13	0.00	0.13	0.13
OK-HILLCREST FERTILITY	6.0	46	46	40	2	0	0.05	0.00	0.05	0.04
OR-EMANUEL HOSPITAL	1.6	20	29	27	4	0	0.15	0.00	0.15	0.14
OR-OR HEALTH SCIENCE UNIV	5.6	56	77	49	3	0	0.06	0.00	0.06	0.04
PA-ALBERT EINSTEIN MED	3.0	30	45	38	6	0	0.16	0.00	0.16	0.13
PA-ENDOCRINE HIST. ASSOC.	1.0	0	0	0	0	0	-	-	-	-
PA-FERT. CTR. ST. LUKES	2.0	0	0	0	0	0	-	-	-	-
PA-HOSPITAL OF U. PENN.	6.5	182	226	186	19	0	0.10	0.00	0.10	0.08
PA-MAGEE-WOMEN'S HOSPITAL	6.0	27	50	32	0	0	0.00	0.00	0.00	0.00
PA-PENN. REPRO. ASSOC.	5.3	213	354	281	31	0	0.11	0.00	0.11	0.09
PA-PITTSBURGH INSTITUTE	1.2	6	5	6	0	0	0.00	0.00	0.00	0.00
PA-WOMEN'S CLINIC LTD.	2.1	31	43	35	5	0	0.14	0.00	0.14	0.11
RI-WOMENS & INFANTS HOSP.	1.0	7	9	9	0	0	0.00	0.00	0.00	0.00
SC-MUSC IVF PROGRAM	4.2	7	15	11	0	1	0.00	0.09	0.09	0.07
SC-SOUTHEASTERN FERTILITY	5.0	38	50	27	1	0	0.04	0.00	0.04	0.02
TN-FAIR (MEMPHIS)	0.2	0	0	0	0	0	-	-	-	-
TN-VANDERBILT MED CTR.	7.0	97	127	98	11	0	0.11	0.00	0.11	0.09
TX-CENTER FOR REPRO. MED.	3.5	31	40	34	5	0	0.15	0.00	0.15	0.13
TX-FT. WORTH INFERT. CTR.	3.7	33	60	31	2	0	0.06	0.00	0.06	0.03
TX-HOUSTON REPRODUCTIVE	6.0	1	2	2	0	0	0.00	0.00	0.00	0.00

TX-J.B. BELUE, M.D.	0.0	0	0	0	0	0	-	-	-	-
TX-OB & GYN ASSOCIATES	6.0	74	103	82	14	0	0.17	0.00	0.17	0.14
TX-PRESB. HOSPITAL DALLAS	4.6	5	9	3	0	0	0.00	0.00	0.00	0.00
TX-SCOTT & WHITE CLINIC	0.2	0	0	0	0	0	-	-	-	-
TX-TRINITY IVF-ET PROGRAM	6.0	49	56	66	10	0	0.15	0.00	0.15	0.18
TX-U OF TEX-SW MED SCHOOL	4.2	14	14	11	0	0	0.00	0.00	0.00	0.00
TX-UNIV. OF TX GALVESTON	5.6	15	15	15	3	0	0.20	0.00	0.20	0.20
UT-UNIVERSITY OF UTAH	5.7	75	96	79	12	0	0.15	0.00	0.15	0.13
VA-HENRICO DRS HOSPITAL	4.6	17	21	14	5	0	0.36	0.00	0.36	0.24
VA-JONES INSTITUTE	8.0	500	737	637	108	0	0.17	0.00	0.17	0.14
VA-MEDICAL COLLEGE OF VA	3.1	24	43	26	1	0	0.04	0.00	0.04	0.02
VA-UNIVERSITY OF VIRGINIA	2.3	7	8	8	0	0	0.00	0.00	0.00	0.00
VT-UNIVERSITY OF VERMONT	2.6	9	12	7	0	0	0.00	0.00	0.00	0.00
WA-FERT CLIN PUGET SOUND	4.0	35	45	39	4	0	0.10	0.00	0.10	0.09
WA-RICE & ASSOCIATES	0.8	0	0	0	0	0	-	-	-	-
WA-SEATTLE FERT & GYN	5.0	68	81	64	8	0	0.13	0.00	0.13	0.10
WA-SEATTLE WOMEN'S CLINIC	1.6	4	4	3	0	0	0.00	0.00	0.00	0.00
WA-SWEDISH HOSP. MED. CTR	5.0	81	103	80	8	0	0.10	0.00	0.10	0.08
WA-UNIV. OF WASHINGTON	5.0	133	175	134	16	0	0.12	0.00	0.12	0.09
WI-APPLETON FAMILY FERT.	2.6	8	11	11	1	0	0.09	0.00	0.09	0.09
WI-UNIV. OF WISCONSIN	6.0	42	68	31	2	0	0.06	0.00	0.06	0.03
WV-W.VIRGINIA UNIVERSITY	1.0	0	0	0	0	0	-	-	-	-
TOTALS	510	8288	12104	9156	1075	34	0.12	0.00	0.12	0.09
AVERAGES	4.93	78.93	115.28	87.00	10.24	0.32	0.12	0.00	0.12	0.08

- Year : years of operation prior to 12/31/88.
- Patients : number of women treated.
- Stim Cyc : (stimulation cycles) an attempt to produce eggs in a women.
- Egg Rec : (egg recoveries) removal of eggs from a woman in order to fertilize them outside of her body.
- Live : number of live births.
- Cont Preg : continuing pregnancies that are ongoing but have not yet resulted in a live birth.
- L/ER : the percentage of egg recoveries that resulted in a live birth.
- C/ER : the percentage of continuing pregnancies that will result if all pregnancies result in a live birth.
- L+C/ER : the percentage of egg recoveries that resulted in a live birth or continuing pregnancy.
- L+C/SC : the percentage of stimulation cycles that resulted in a live birth or continuing pregnancy.

CHART III

1988 IVF DATA

NAME	Year	Patients	Stim Cyc	Egg Rec	Live	Cont Preg	L/ER	C/ER	L+C/ER	L+C/SC
AL-ASSISTED REPRODUCTIVE	2.2	184	219	181	29	23	0.16	0.13	0.29	0.24
AL-UNIV. OF AL BIRMINGHAM	6.0	26	39	21	0	4	0.00	0.19	0.19	0.10
AL-UNIV. OF S. ALABAMA	1.6	18	23	21	0	0	0.00	0.00	0.00	0.00
AZ-ARIZONA FERTILITY INST	6.0	90	117	106	4	8	0.04	0.07	0.11	0.10
AZ-REPRO. INST. OF TUCSON	3.0	9	10	7	0	1	0.00	0.14	0.14	0.10
AZ-SOUTHWEST FERTILITY	0.5	4	6	4	0	1	0.00	0.25	0.25	0.17
CA-ALTA BATES HOSPITAL	5.0	123	141	114	13	14	0.11	0.12	0.24	0.19
CA-AMI-SOUTHBAY HOSPITAL	2.0	110	147	122	9	20	0.07	0.16	0.24	0.20
CA-CAL-IRVINE IVF/GIFT	2.5	183	263	180	4	25	0.02	0.13	0.16	0.11
CA-CEDARS-SINAI MED CENTR	2.4	123	130	90	6	8	0.07	0.09	0.16	0.11
CA-CENTRAL CA IVF PROGRAM	4.0	90	98	86	3	10	0.03	0.12	0.15	0.13
CA-CENTURY CITY HOSPITAL	6.0	132	166	152	11	18	0.07	0.12	0.19	0.17
CA-FERT & REPRO. HEALTH	0.3	13	13	13	0	4	0.00	0.30	0.30	0.30
CA-FOREST FERTILITY CENT.	1.0	8	9	9	0	1	0.00	0.11	0.11	0.11
CA-HOAG FERTILITY SERVICE	1.3	29	52	29	3	6	0.10	0.21	0.31	0.17
CA-HOSPITAL OF GOOD SAM.	8.0	164	206	140	0	18	0.00	0.13	0.13	0.09
CA-JOHN MUIR MEMORIAL	4.7	180	390	300	16	47	0.05	0.16	0.21	0.16
CA-NORTH. CALIF. FERT.	6.0	38	42	30	0	4	0.00	0.13	0.13	0.10
CA-NORTHRIDGE HOSPITAL	4.5	77	185	153	26	12	0.17	0.08	0.25	0.21
CA-NOVA FERTILITY CENTER	1.2	59	90	54	4	12	0.07	0.22	0.30	0.18
CA-PACIFIC FERTILITY CENT	1.0	84	123	102	6	16	0.06	0.16	0.22	0.18
CA-S. CAL. FERTILITY INS.	4.0	12	17	12	1	2	0.08	0.17	0.25	0.18
CA-UCLA MEDICAL CENTER	5.3	72	106	98	8	8	0.08	0.08	0.16	0.15
CA-UCSF FERTILITY ASSOC.	6.0	158	216	142	6	20	0.04	0.14	0.18	0.12
CA-WHITTIER HOSPITAL	1.0	9	13	8	0	1	0.00	0.13	0.13	0.08
CO-REPRODUCTIVE GENETICS	6.3	161	364	300	16	17	0.05	0.07	0.12	0.09
CT-MT. SINAI HOSPITAL	4.6	47	47	39	1	2	0.03	0.05	0.08	0.06
CT-UCONN SCHOOL OF MED.	6.0	41	88	47	3	3	0.06	0.06	0.13	0.07
CT-YALE SCHOOL OF MED.	5.5	293	406	342	23	14	0.07	0.04	0.11	0.09
DC-COLUMBIA HOS FOR WOMEN	2.0	94	162	134	4	15	0.03	0.11	0.14	0.12
DC-GW UNIVERSITY IVF	6.0	67	81	50	1	9	0.02	0.18	0.20	0.12
FL-FERT CEN OF BOCA RATON	1.1	20	36	31	1	3	0.03	0.10	0.13	0.11
FL-FLORIDA FERTILITY	1.2	18	20	12	0	0	0.00	0.00	0.00	0.00
FL-HUMANA WOMEN'S HOSPIT.	3.0	62	88	60	6	6	0.10	0.10	0.20	0.14
FL-JACKSONVILLE MEM MED	2.6	10	14	9	1	1	0.11	0.11	0.22	0.14
FL-N.W. FLA. GULF BREEZE	1.3	36	38	31	2	4	0.06	0.13	0.19	0.16
FL-NW CENTER FOR INFERT.	1.4	79	104	70	3	6	0.04	0.09	0.13	0.09
FL-PARK AVE. WOMENS CENTR	0.2	6	7	0	0	1	-	-	-	0.14
FL-SAND LAKE IVF CENTER	2.3	118	143	114	0	11	0.00	0.10	0.10	0.08
GA-AUGUSTA REPROD. BIO.	5.0	30	36	32	5	7	0.16	0.22	0.38	0.33
GA-MEDICAL COLLEGE OF GA	5.0	28	36	19	0	1	0.00	0.05	0.05	0.03
GA-REPRODUCTIVE BIOLOGY	6.0	329	389	227	11	46	0.05	0.20	0.25	0.15
HI-KAUAI MEDICAL GROUP	4.0	5	5	5	0	0	0.00	0.00	0.00	0.00
HI-PACIFIC IVF INSTITUTE	3.5	105	105	88	10	8	0.11	0.09	0.20	0.17
IA-UNIVERSITY IOWA	1.4	56	88	62	0	10	0.00	0.16	0.16	0.11
IL-EVANSTON AND GLENBROOK	2.0	97	110	100	5	15	0.05	0.15	0.20	0.18
IL-MASONIC MEDICAL CENTER	2.1	76	117	90	4	9	0.04	0.10	0.14	0.11
IL-MICHAEL REESE HOSPITAL	6.0	99	138	132	1	5	0.01	0.04	0.06	0.06
IL-NORTHWESTERN MEMORIAL	2.0	15	18	11	4	1	0.36	0.09	0.45	0.28
IL-RUSH PRESB-ST. LUKE'S	6.1	72	72	72	2	5	0.03	0.07	0.10	0.10
IL-U. OF ILLINOIS MED. C.	4.2	6	7	4	0	0	0.00	0.00	0.00	0.00
IN-CENTER FOR REPROD.	1.2	28	37	36	0	3	0.00	0.08	0.08	0.08
IN-INDIANA UNIVERSITY	6.0	3	3	2	0	0	0.00	0.00	0.00	0.00
IN-PREGNANCY INITIATION	3.0	153	210	161	8	11	0.05	0.07	0.12	0.09
KS-REPROD. RESOUCE CENTER	1.3	67	121	97	12	11	0.12	0.11	0.24	0.19
KS-UNIV. KANSAS WICHITA	1.6	16	22	14	1	5	0.07	0.36	0.43	0.27
KY-FERTILITY INSTITUTE	2.1	1	1	1	0	0	0.00	0.00	0.00	0.00
KY-NORTON HOSPITAL	6.0	49	66	62	8	9	0.13	0.15	0.27	0.26

KY-UNIVERSITY OF KENTUCKY	4.0	56	79	59	2	4	0.03	0.07	0.10	0.08
LA-FERT INST NEW ORLEANS	6.0	66	78	67	4	10	0.06	0.15	0.21	0.18
MA-ALTANTICARE FERTILITY	0.7	71	103	94	1	8	0.01	0.09	0.10	0.09
MA-BRIGHAM & WOMEN'S HOS.	6.0	126	131	73	14	8	0.19	0.11	0.30	0.17
MA-NEW ENGLAND MED. CTR.	1.9	12	17	16	0	2	0.00	0.13	0.13	0.12
MD-UNIVERSITY OF MARYLAND	0.3	2	2	2	0	0	0.00	0.00	0.00	0.00
MD-WOMEN'S HOSPITAL CENTR	4.3	241	364	354	24	48	0.07	0.14	0.20	0.20
MI-BLODGETT MEMORIAL IVF	5.4	43	61	44	8	5	0.18	0.11	0.30	0.26
MI-HUTZEL HOST./WAYNE ST.	6.5	92	112	92	2	4	0.02	0.04	0.07	0.05
MI-OAKWOOD HOSPITAL	0.1	1	1	1	0	0	0.00	0.00	0.00	0.00
MI-SOMI REPROD. ENDO.	1.6	49	79	74	2	10	0.03	0.14	0.16	0.15
MI-UNIV MI MEDICAL CENTER	6.0	66	83	61	2	3	0.03	0.05	0.08	0.08
MI-WILLIAM BEAUMONT HOSP.	5.5	124	153	119	2	7	0.02	0.06	0.08	0.08
MN-U. OF MINNESOTA	6.0	125	139	103	2	10	0.02	0.10	0.12	0.09
MO-WASHINGTON U. JEWISH	6.0	62	97	56	4	2	0.07	0.04	0.11	0.06
MS-U. MISS MEDICAL CENTER	6.0	43	66	48	2	6	0.04	0.13	0.17	0.12
NC-DUKE UNIVERSITY MED.	6.0	65	75	52	1	5	0.02	0.10	0.12	0.09
NC-NC MEMORIAL HOSPITAL	6.0	0	0	0	0	0	-	-	-	-
NC-NC REPROD. CENTER	1.7	5	8	5	0	2	0.00	0.40	0.40	0.25
NE-METHODIST HOSPITAL	1.6	12	19	17	0	2	0.00	0.12	0.12	0.11
NE-UNIVERSITY OF NEBRASKA	1.0	25	50	40	1	1	0.02	0.02	0.05	0.04
NH-DARTMOUTH-HITCHCOCK	3.0	9	10	6	1	1	0.17	0.17	0.33	0.20
NJ-ROBERT WOOD JOHNSON	5.5	90	226	101	11	2	0.11	0.02	0.13	0.06
NJ-UMDNJ NJ MED SCHOOL	2.7	128	168	158	8	14	0.05	0.09	0.14	0.13
NM-PRESBYTERIAN IVF	2.0	20	24	29	1	4	0.03	0.14	0.17	0.15
NY-NORTHERN NY FERTILITY	6.0	111	186	123	8	14	0.07	0.11	0.18	0.14
NY-ALBERT EINSTEIN COLL	2.6	40	67	55	0	6	0.00	0.11	0.11	0.09
NY-AUSTRALIA,UNITED HOSP.	2.7	656	867	807	20	120	0.02	0.15	0.17	0.15
NY-CHILDREN'S HOS. (BUFF)	1.0	24	30	22	0	0	0.00	0.00	0.00	0.00
NY-COLUMBIA PRESBYTERIAN	6.8	29	71	54	8	4	0.15	0.07	0.22	0.17
NY-LIFE PROGRAM	0.6	11	15	15	0	0	0.00	0.00	0.00	0.00
NY-MT. SINAI HOSPITAL	2.1	210	311	230	9	21	0.03	0.06	0.09	0.10
NY-NY HOSPITAL-CORNELL	2.0	142	313	244	2	24	0.01	0.10	0.11	0.09
NY-ST. LUKE'S ROOSEVELT	4.0	19	33	20	0	0	0.00	0.00	0.00	0.00
NY-U. OF ROCHESTER CARE	5.5	54	63	60	1	4	0.02	0.07	0.08	0.08
NY-WAYNE DECKER IVF PRGRM	1.6	37	53	37	1	4	0.03	0.11	0.14	0.09
OH-AKRON CITY HOSPITAL	3.5	55	90	52	10	10	0.19	0.19	0.38	0.22
OH-BETHESDA FERTILITY	1.5	37	48	41	0	5	0.00	0.12	0.12	0.10
OH-CLEVELAND CLINIC FOUND	4.1	90	141	112	10	6	0.09	0.05	0.14	0.11
OH-JEWISH HOSP. OF CIN.	5.1	5	5	5	0	1	0.00	0.20	0.20	0.20
OH-MACDONALD HOSP.	4.1	49	96	50	0	5	0.00	0.10	0.10	0.06
OH-MIAMI VALLEY HOSPITAL	4.8	21	46	41	2	3	0.05	0.07	0.12	0.11
OH-MIDWEST REPROD. INST.	5.9	34	43	27	0	2	0.00	0.07	0.07	0.05
OH-MT. SINAI MED. CENTER	6.0	30	50	48	2	4	0.04	0.08	0.13	0.10
OH-RIVERSIDE REPROD. SERV	1.2	27	51	38	1	1	0.03	0.03	0.05	0.04
OH-UNIV REPROD. CENTER	6.3	90	136	102	4	2	0.04	0.02	0.06	0.04
OK-HENRY BENNETT FERTILTY	2.7	24	31	19	1	0	0.05	0.00	0.05	0.03
OK-HILLCREST FERTILITY	6.0	52	52	50	0	7	0.00	0.14	0.14	0.13
OR-EMANUEL HOSPITAL	1.6	40	66	54	2	4	0.04	0.07	0.11	0.09
OR-OR HEALTH SCIENCE UNIV	6.6	56	63	53	3	9	0.06	0.17	0.23	0.19
PA-ALBERT EINSTEIN MED	2.9	50	67	57	3	3	0.05	0.05	0.11	0.09
PA-ENDOCRINE HIST. ASSOC.	1.0	120	211	200	1	16	0.00	0.08	0.08	0.08
PA-FERT. CTR. ST. LUKES	2.0	7	10	0	0	0	-	-	-	0.00
PA-HOSPITAL OF U. PENN.	6.5	196	310	284	14	24	0.05	0.09	0.14	0.12
PA-MAGEE-WOMEN'S HOSPITAL	6.0	100	139	100	3	12	0.03	0.12	0.15	0.11
PA-PENN. REPRO. ASSOC.	6.3	283	479	389	12	33	0.03	0.09	0.12	0.09
PA-PITTSBURGH INSTITUTE	1.2	10	12	10	0	2	0.00	0.20	0.20	0.17
PA-WOMEN'S CLINIC LTD.	2.1	46	69	60	3	4	0.05	0.07	0.12	0.10
RI-WOMENS & INFANTS HOSP.	1.8	11	14	13	0	3	0.00	0.23	0.23	0.21
SC-MUSC IVF PROGRAM	4.2	10	13	11	2	1	0.18	0.09	0.27	0.22
SC-SOUTHEASTERN FERTILITY	6.0	52	62	41	1	1	0.02	0.02	0.05	0.02
TN-FAIR (MEMPHIS)	0.2	12	14	12	0	0	0.00	0.00	0.00	0.00
TN-VANDERBILT MED CTR.	7.0	97	126	116	12	12	0.10	0.10	0.21	0.19
TX-CENTER FOR REPRO. MED.	2.5	52	63	56	5	3	0.09	0.05	0.14	0.13
TX-FT. WORTH INFERT. CTR.	2.7	30	66	37	1	1	0.03	0.03	0.06	0.05
TX-HOUSTON REPRODUCTIVE	5.0	19	31	16	0	4	0.00	0.25	0.25	0.19

TX-J.B. BELUE, M.D.	0.0	0	0	0	0	0	-	-	-	-
TX-OB & GYN ASSOCIATES	8.0	147	180	170	13	26	0.08	0.15	0.23	0.21
TX-PRESB. HOSPITAL DALLAS	4.6	3	3	3	0	0	0.00	0.00	0.00	0.00
TX-SCOTT & WHITE CLINIC	0.2	3	4	3	0	1	0.00	0.33	0.33	0.25
TX-TRINITY IVF-ET PROGRAM	6.0	118	133	107	7	7	0.07	0.07	0.13	0.11
TX-U OF TEX-SW MED SCHOOL	4.2	30	30	26	0	5	0.00	0.19	0.19	0.17
TX-UNIV. OF TX GALVESTON	5.0	0	0	0	0	0	-	-	-	-
UT-UNIVERSITY OF UTAH	5.7	88	104	72	9	15	0.13	0.21	0.33	0.23
VA-HENRICO DRS HOSPITAL	4.6	28	38	30	4	4	0.13	0.13	0.27	0.21
VA-JONES INSTITUTE	8.0	600	783	706	21	88	0.03	0.12	0.15	0.14
VA-MEDICAL COLLEGE OF VA	2.1	30	33	30	10	6	0.33	0.20	0.53	0.48
VA-UNIVERSITY OF VIRGINIA	2.3	3	3	3	0	1	0.00	0.33	0.33	0.33
VT-UNIVERSITY OF VERMONT	2.4	6	7	6	0	0	0.00	0.00	0.00	0.00
WA-FERT CLIN PUGET SOUND	4.0	16	17	17	0	1	0.06	0.06	0.06	0.06
WA-RICE & ASSOCIATES	0.8	1	1	0	0	0	-	-	-	0.00
WA-SEATTLE FERT & GYN	6.0	109	130	98	7	12	0.07	0.12	0.19	0.16
WA-SEATTLE WOMEN'S CLINIC	1.6	1	1	1	0	0	0.00	0.00	0.00	0.00
WA-SWEDISH HOSP. MED. CTR	5.0	124	148	112	9	13	0.08	0.11	0.19	0.14
WA-UNIV. OF WASHINGTON	6.0	152	196	139	10	12	0.07	0.08	0.16	0.11
WI-APPLETON FAMILY FERT.	2.6	8	8	8	0	0	0.00	0.00	0.00	0.00
WI-UNIV. OF WISCONSIN	6.0	60	78	36	2	1	0.05	0.03	0.08	0.04
WV-W.VIRGINIA UNIVERSITY	1.0	17	28	19	0	1	0.00	0.05	0.05	0.04
TOTALS	518	10386	14619	11006	600	1231	0.06	0.11	0.16	0.13
AVERAGES	4.10	82.94	117.00	88.00	4.81	9.93	0.06	0.11	0.16	0.13

- Year : years of operation prior to 12/31/88.
- Patients : number of women treated.
- Stim Cyc : (stimulation cycles) an attempt to produce eggs in a woman.
- Egg Rec : (egg recoveries) removal of eggs from a woman in order to fertilize them outside of her body.
- Live : number of live births.
- Cont Preg : continuing pregnancies that are ongoing but have not yet resulted in a live birth.
- L/ER : the percentage of egg recoveries that resulted in a live birth.
- C/ER : the percentage of continuing pregnancies that will result if all pregnancies result in a live birth.
- LoC/ER : the percentage of egg recoveries that resulted in a live birth or continuing pregnancy.
- LoC/SC : the percentage of stimulation cycles that resulted in a live birth or continuing pregnancy.

CHART IV

1987 GIFT DATA

NAME	Year	Patients	Stim Cyc	Egg Rec	Live	Cont Preg	L/ER	C/ER	L+C/ER	L+C/SC
AL-ASSISTED REPRODUCTIVE	0.2	0	0	0	0	0	-	-	-	-
AL-UNIV. OF AL BIRMINGHAM	2.0	6	8	4	1	0	0.25	0.00	0.25	0.13
AL-UNIV. OF S. ALABAMA	1.2	1	1	1	0	0	0.00	0.00	0.00	0.00
AZ-ARIZONA FERTILITY INST	4.0	9	12	8	1	0	0.13	0.00	0.13	0.08
AZ-REPRO. INST. OF TUCSON	3.0	10	10	7	2	0	0.29	0.00	0.29	0.20
AZ-SOUTHWEST FERTILITY	2.1	25	31	16	3	0	0.19	0.00	0.19	0.10
CA-ALTA BATES HOSPITAL	3.0	2	2	2	0	0	0.00	0.00	0.00	0.00
CA-AMI-SOUTHBAY HOSPITAL	1.7	3	3	3	1	0	0.33	0.00	0.33	0.33
CA-CAL-IRVINE IVF/GIFT	2.5	138	188	151	29	0	0.19	0.00	0.19	0.15
CA-CEDARS-SINAI MED CENTR	2.4	0	0	0	0	0	-	-	-	-
CA-CENTRAL CA IVF PROGRAM	3.0	18	18	9	2	0	0.22	0.00	0.22	0.11
CA-CENTURY CITY HOSPITAL	2.0	37	47	47	0	0	0.00	0.00	0.00	0.00
CA-FERT & REPRO. HEALTH	0.2	0	0	0	0	0	-	-	-	-
CA-FOREST FERTILITY CENT.	3.0	8	8	8	0	0	0.00	0.00	0.00	0.00
CA-HOAG FERTILITY SERVICE	1.2	5	9	4	0	0	0.00	0.00	0.00	0.00
CA-HOSPITAL OF GOOD SAM.	3.0	0	417	219	42	0	0.19	0.00	0.19	0.10
CA-JOHN MUIR MEMORIAL	3.5	8	22	15	3	0	0.20	0.00	0.20	0.14
CA-NORTH. CALIF. FERT.	1.0	0	0	0	0	0	-	-	-	-
CA-NORTHRIDGE HOSPITAL	2.4	7	14	11	0	0	0.00	0.00	0.00	0.00
CA-NOVA FERTILITY CENTER	1.2	4	4	3	0	0	0.00	0.00	0.00	0.00
CA-PACIFIC FERTILITY CENT	0.0	0	0	0	0	0	-	-	-	-
CA-S. CAL. FERTILITY INS.	2.0	10	10	10	0	3	0.00	0.30	0.30	0.30
CA-UCLA MEDICAL CENTER	5.0	2	2	2	0	0	0.00	0.00	0.00	0.00
CA-UCSF FERTILITY ASSOC.	2.0	6	6	6	1	0	0.17	0.00	0.17	0.17
CA-WHITTIER HOSPITAL	1.0	0	0	0	0	0	-	-	-	-
CO-REPRODUCTIVE GENETICS	0.0	0	0	0	0	0	-	-	-	-
CT-MT. SINAI HOSPITAL	1.7	5	5	4	0	0	0.00	0.00	0.00	0.00
CT-UCONN SCHOOL OF MED.	4.0	8	8	8	1	0	0.13	0.00	0.13	0.12
CT-YALE SCHOOL OF MED.	3.5	33	40	26	1	0	0.04	0.00	0.04	0.03
DC-COLUMBIA HOS FOR WOMEN	2.0	0	0	0	0	0	-	-	-	-
DC-GW UNIVERSITY IVF	3.0	10	10	10	2	0	0.20	0.00	0.20	0.20
FL-FERT CEN OF BOCA RATON	0.8	0	0	0	0	0	-	-	-	-
FL-FLORIDA FERTILITY	1.2	29	33	28	0	0	0.00	0.00	0.00	0.00
FL-HUMANA WOMEN'S HOSPIT.	2.5	3	3	3	0	0	0.00	0.00	0.00	0.00
FL-JACKSONVILLE MEM MED	1.6	28	33	32	1	0	0.03	0.00	0.03	0.03
FL-N.W. FLA. GULF BREEZE	1.3	15	15	10	0	0	0.00	0.00	0.00	0.00
FL-NW CENTER FOR INFERT.	1.4	13	13	11	0	2	0.00	0.18	0.18	0.15
FL-PARK AVE. WOMENS CENTR	0.3	0	0	0	0	0	-	-	-	-
FL-SAND LAKE IVF CENTER	2.1	2	2	2	0	0	0.00	0.00	0.00	0.00
GA-AUGUSTA REPROD. BIO.	0.0	0	0	0	0	0	-	-	-	-
GA-MEDICAL COLLEGE OF GA	2.5	1	1	1	0	0	0.00	0.00	0.00	0.00
GA-REPRODUCTIVE BIOLOGY	3.0	9	48	9	2	0	0.22	0.00	0.22	0.04
HI-KAUAI MEDICAL GROUP	2.0	0	0	0	0	0	-	-	-	-
HI-PACIFIC IVF INSTITUTE	0.0	0	0	0	0	0	-	-	-	-
IA-UNIVERSITY IOWA	1.4	4	5	4	0	0	0.00	0.00	0.00	0.00
IL-EVANSTON AND GLENBROOK	0.6	0	0	0	0	0	-	-	-	-
IL-MASONIC MEDICAL CENTER	1.0	18	21	15	0	0	0.00	0.00	0.00	0.00
IL-MICHAEL REESE HOSPITAL	2.0	6	6	5	1	0	0.20	0.00	0.20	0.17
IL-NORTHWESTERN MEMORIAL	2.0	26	26	20	0	0	0.00	0.00	0.00	0.00
IL-RUSH PRESB-ST. LUKE'S	1.4	19	19	19	0	0	0.00	0.00	0.00	0.00
IL-U. OF ILLINOIS MED. C.	3.2	3	2	1	0	0	0.00	0.00	0.00	0.00
IN-CENTER FOR REPROD.	1.2	4	6	6	0	0	0.00	0.00	0.00	0.00
IN-INDIANA UNIVERSITY	2.0	1	1	1	0	0	0.00	0.00	0.00	0.00
IN-PREGNANCY INITIATION	3.0	208	282	192	20	0	0.10	0.00	0.10	0.07
KS-REPROD. RESOUCE CENTER	2.9	55	69	49	3	0	0.06	0.00	0.06	0.04
KS-UNIV. KANSAS WICHITA	2.0	22	34	27	4	0	0.15	0.00	0.15	0.12
KY-FERTILITY INSTITUTE	2.3	23	46	46	6	0	0.13	0.00	0.13	0.13
KY-NORTON HOSPITAL	3.0	1	1	1	1	1	1.00	1.00	2.00	2.00

KY-UNIVERSITY OF KENTUCKY	2.7	44	58	36	5	0	0.14	0.00	0.14	0.09
LA-FERT INST NEW ORLEANS	4.0	205	288	144	26	0	0.18	0.00	0.18	0.09
MA-ALTANTICARE FERTILITY	0.0	0	0	0	0	0	-	-	-	-
MA-BRIGHAM & WOMEN'S HOS.	3.0	9	9	8	1	0	0.13	0.00	0.13	0.11
MA-NEW ENGLAND MED. CTR.	1.4	0	0	0	0	0	-	-	-	-
MD-UNIVERSITY OF MARYLAND	0.3	0	0	0	0	0	-	-	-	-
MD-WOMEN'S HOSPITAL CENTR	2.6	19	23	23	3	0	0.13	0.00	0.13	0.13
MI-BLODGETT MEMORIAL IVF	0.0	0	0	0	0	0	-	-	-	-
MI-HUTZEL HOST./WAYNE ST.	3.2	1	1	1	0	0	0.00	0.00	0.00	0.00
MI-OAKWOOD HOSPITAL	0.0	0	0	0	0	0	-	-	-	-
MI-SCRI REPROD. ENDO.	1.6	34	45	42	10	0	0.24	0.00	0.24	0.22
MI-UNIV MI MEDICAL CENTER	3.0	2	2	2	0	0	0.00	0.00	0.00	0.00
MI-WILLIAM BEAUMONT HOSP.	2.1	2	2	2	1	0	0.50	0.00	0.50	0.50
MN-U. OF MINNESOTA	4.0	0	0	0	0	0	-	-	-	-
MO-WASHINGTON U. JEWISH	2.0	2	2	2	0	0	0.00	0.00	0.00	0.00
MS-U. MISS MEDICAL CENTER	4.0	2	2	1	1	0	1.00	0.00	1.00	0.50
NC-DUKE UNIVERSITY MED.	4.0	10	10	9	1	0	0.11	0.00	0.11	0.10
NC-NC MEMORIAL HOSPITAL	3.0	23	25	25	3	2	0.12	0.00	0.20	0.20
NC-NC REPROD. CENTER	0.0	0	0	0	0	0	-	-	-	-
NE-METHODIST HOSPITAL	1.4	2	41	2	0	0	0.00	0.00	0.00	0.00
NE-UNIVERSITY OF NEBRASKA	0.5	0	0	0	0	0	-	-	-	-
NH-DARTMOUTH-HITCHCOCK	0.0	0	0	0	0	0	-	-	-	-
NJ-ROBERT WOOD JOHNSON	3.5	0	0	0	0	0	-	-	-	-
NJ-UMDNJ NJ MED SCHOOL	1.0	1	1	1	0	0	0.00	0.00	0.00	0.00
NM-PRESBYTERIAN IVF	3.0	0	0	0	0	0	-	-	-	-
NY-NORTHERN NY FERTILITY	3.0	5	5	5	0	0	0.00	0.00	0.00	0.00
NY-ALBERT EINSTEIN COLL	2.0	29	45	33	11	11	0.33	0.33	0.67	0.48
NY-AUSTRALIA,UNITED HOSP.	0.0	0	0	0	0	0	-	-	-	-
NY-CHILDREN'S HOS. (BUFF)	3.0	0	0	0	0	0	-	-	-	-
NY-COLUMBIA PRESBYTERIAN	2.2	0	0	0	0	0	-	-	-	-
NY-LIFE PROGRAM	0.6	0	0	0	0	0	-	-	-	-
NY-MT. SINAI HOSPITAL	1.5	18	18	18	4	0	0.22	0.00	0.22	0.22
NY-NY HOSPITAL-CORNELL	3.0	27	30	30	4	0	0.13	0.00	0.13	0.13
NY-ST. LUKE'S ROOSEVELT	3.0	1	1	1	0	0	0.00	0.00	0.00	0.00
NY-U. OF ROCHESTER CARE	1.2	2	2	2	0	0	0.00	0.00	0.00	0.00
NY-WAYNE DECKER IVF PROGM	0.0	0	0	0	0	0	-	-	-	-
OH-AKRON CITY HOSPITAL	2.0	1	1	1	0	0	0.00	0.00	0.00	0.00
OH-BETHESDA FERTILITY	1.5	11	15	9	2	0	0.22	0.00	0.22	0.13
OH-CLEVELAND CLINIC FOUND	2.6	2	2	2	1	0	0.50	0.00	0.50	0.50
OH-JEWISH HOSP. OF CIN.	0.0	16	16	15	0	0	0.00	0.00	0.00	0.00
OH-MACDONALD HOSP.	4.0	0	0	0	0	0	-	-	-	-
OH-MIAMI VALLEY HOSPITAL	1.6	11	13	10	3	0	0.30	0.00	0.30	0.23
OH-MIDWEST REPROD. INST.	3.0	41	47	13	3	0	0.23	0.00	0.23	0.06
OH-MT. SINAI MED. CENTER	2.0	33	46	30	4	0	0.13	0.00	0.13	0.11
OH-RIVERSIDE REPROD. SERV	1.5	14	16	13	0	0	0.00	0.00	0.00	0.00
OH-UNIV REPROD. CENTER	2.0	30	47	30	1	0	0.03	0.00	0.03	0.02
OK-HENRY BENNETT FERTILTY	2.0	34	45	30	2	0	0.07	0.00	0.07	0.04
OK-HILLCREST FERTILITY	2.3	0	0	0	0	0	-	-	-	-
OR-EMANUEL HOSPITAL	1.3	2	2	2	0	0	0.00	0.00	0.00	0.00
OR-OR HEALTH SCIENCE UNIV	2.3	21	32	16	2	0	0.13	0.00	0.13	0.06
PA-ALBERT EINSTEIN MED	1.6	2	2	2	0	0	0.00	0.00	0.00	0.00
PA-ENDOCRINE HIST. ASSOC.	0.0	0	0	0	0	0	-	-	-	-
PA-FERT. CTR. ST. LUKES	3.0	0	0	60	3	0	0.05	0.00	0.05	-
PA-HOSPITAL OF U. PENN.	3.2	16	18	16	0	0	0.00	0.00	0.00	0.00
PA-MAGEE-WOMEN'S HOSPITAL	2.0	42	62	40	0	0	0.00	0.00	0.00	0.00
PA-PENN. REPRO. ASSOC.	3.7	134	106	130	29	0	0.22	0.00	0.22	0.17
PA-PITTSBURGH INSTITUTE	0.0	0	0	0	0	0	-	-	-	-
PA-WOMEN'S CLINIC LTD.	0.0	0	0	0	0	0	-	-	-	-
RI-WOMENS & INFANTS HOSP.	0.0	0	0	0	0	0	-	-	-	-
SC-MUSC IVF PROGRAM	0.0	0	0	0	0	0	-	-	-	-
SC-SOUTHEASTERN FERTILITY	3.0	12	13	11	2	0	0.18	0.00	0.18	0.15
TN-PAIR (MEMPHIS)	0.5	3	3	3	0	0	0.00	0.00	0.00	0.00
TN-VANDERBILT MED CTR.	3.0	24	25	25	1	0	0.04	0.00	0.04	0.03
TX-CENTER FOR REPRO. MED.	2.3	18	30	33	0	2	0.00	0.00	0.06	0.00
TX-FT. WORTH INFERT. CTR.	1.3	8	8	8	0	0	0.00	0.00	0.00	0.00
TX-HOUSTON REPRODUCTIVE	4.0	4	4	4	0	0	0.00	0.00	0.00	0.00

IA-J.D. [illegible], M.D.	2.2	13	20	13	2	0	0.15	0.00	0.15	0.10
TX-OB & GYN ASSOCIATES	4.0	80	125	102	22	0	0.22	0.00	0.22	0.18
TX-PRESB. HOSPITAL DALLAS	3.4	45	50	31	11	0	0.35	0.00	0.35	0.22
TX-SCOTT & WHITE CLINIC	0.2	0	0	0	0	0	-	-	-	-
TX-TRINITY IVF-ET PROGRAM	4.0	4	4	4	0	0	0.00	0.00	0.00	0.00
TX-U OF TEX-SW MED SCHOOL	2.0	7	7	7	0	0	0.00	0.00	0.00	0.00
TX-UNIV. OF TX GALVESTON	2.0	3	3	3	1	0	0.33	0.00	0.33	0.33
UT-UNIVERSITY OF UTAH	2.6	13	18	20	4	0	0.20	0.00	0.20	0.22
VA-HENRICO DRS HOSPITAL	2.9	10	12	11	3	0	0.27	0.00	0.27	0.25
VA-JONES INSTITUTE	3.0	1	1	1	0	0	0.00	0.00	0.00	0.00
VA-MEDICAL COLLEGE OF VA	0.3	0	0	0	0	0	-	-	-	-
VA-UNIVERSITY OF VIRGINIA	1.7	3	4	4	0	0	0.00	0.00	0.00	0.00
VT-UNIVERSITY OF VERMONT	2.7	1	1	1	0	0	0.00	0.00	0.00	0.00
WA-FERT CLIN PUGET SOUND	4.0	72	111	103	0	0	0.00	0.00	0.00	0.00
WA-RICE & ASSOCIATES	0.3	0	0	1	0	0	0.00	0.00	0.00	-
WA-SEATTLE FERT & GYN	3.4	109	141	96	27	0	0.28	0.00	0.28	0.19
WA-SEATTLE WOMEN'S CLINIC	1.0	6	6	4	1	0	0.25	0.00	0.25	0.17
WA-SWEDISH HOSP. MED. CTR	3.4	188	204	137	34	0	0.25	0.00	0.25	0.17
WA-UNIV. OF WASHINGTON	2.0	9	10	7	0	0	0.00	0.00	0.00	0.00
WI-APPLETON FAMILY FERT.	1.2	1	1	1	0	0	0.00	0.00	0.00	0.00
WI-UNIV. OF WISCONSIN	1.0	0	0	0	0	0	-	-	-	-
WV-W.VIRGINIA UNIVERSITY	1.0	0	0	0	0	0	-	-	-	-
TOTALS	286	2310	3408	2340	256	21	0.14	0.01	0.15	0.11
AVERAGES	3.31	28.07	38.76	28.32	3.06	0.23	0.14	0.01	0.15	0.11

- Year : years of operation prior to 12/31/88.
- Patients : number of women treated.
- Stim Cyc : (stimulation cycles) an attempt to produce eggs in a woman.
- Egg Rec : (egg recoveries) removal of eggs from a woman in order to fertilize them outside of her body.
- Live : number of live births.
- Cont Preg : continuing pregnancies that are ongoing but have not yet resulted in a live birth.
- L/ER : the percentage of egg recoveries that resulted in a live birth.
- C/ER : the percentage of continuing pregnancies that will result if all pregnancies result in a live birth.
- L+C/ER : the percentage of egg recoveries that resulted in a live birth or continuing pregnancy.
- L+C/SC : the percentage of stimulation cycles that resulted in a live birth or continuing pregnancy.

CHART V

1988 GIFT DATA

NAME	Year	Patients	Stim Cyc	Egg Ret	Live	Cont Preg	L/ER	C/ER	L+C/ER	L+C/SC
AL-ASSISTED REPRODUCTIVE	0.3	8	8	8	0	1	0.00	0.13	0.13	0.13
AL-UNIV. OF AL BIRMINGHAM	2.0	24	36	22	0	4	0.00	0.18	0.18	0.11
AL-UNIV. OF S. ALABAMA	1.3	1	1	1	0	0	0.00	0.00	0.00	0.00
AZ-ARIZONA FERTILITY INST	4.0	1	1	1	0	0	0.00	0.00	0.00	0.00
AZ-REPRO. INST. OF TUCSON	3.0	5	5	5	0	1	0.00	0.20	0.20	0.20
AZ-SOUTHWEST FERTILITY	2.1	33	41	31	1	3	0.03	0.10	0.13	0.10
CA-ALTA BATES HOSPITAL	3.0	2	2	2	0	0	0.00	0.00	0.00	0.00
CA-AMI-SOUTHBAY HOSPITAL	1.7	3	3	3	1	0	0.33	0.00	0.33	0.33
CA-CAL-IRVINE IVF/GIFT	2.5	193	248	155	10	30	0.06	0.19	0.26	0.16
CA-CEDARS-SINAI MED CENTR	2.4	112	123	83	19	2	0.23	0.02	0.25	0.17
CA-CENTRAL CA IVF PROGRAM	3.0	36	35	28	2	8	0.07	0.29	0.36	0.29
CA-CENTURY CITY HOSPITAL	2.0	133	146	146	16	17	0.11	0.12	0.23	0.22
CA-FERT & REPRO. HEALTH	0.3	1	1	0	0	0	-	-	-	0.00
CA-FOREST FERTILITY CENT.	3.0	1	1	1	0	0	0.00	0.00	0.00	0.00
CA-HOAG FERTILITY SERVICE	1.3	15	21	7	0	3	0.00	0.43	0.43	0.14
CA-HOSPITAL OF GOOD SAM.	3.0	160	200	125	0	25	0.00	0.20	0.20	0.12
CA-JOHN MUIR MEMORIAL	2.5	4	14	10	1	1	0.10	0.10	0.20	0.14
CA-NORTH. CALIF. FERT.	1.0	22	26	18	1	2	0.06	0.11	0.17	0.12
CA-NORTHRIDGE HOSPITAL	2.5	35	35	30	1	8	0.03	0.27	0.30	0.26
CA-NOVA FERTILITY CENTER	1.3	12	13	9	2	2	0.22	0.22	0.44	0.31
CA-PACIFIC FERTILITY CENT	0.0	0	0	0	0	0	-	-	-	-
CA-S. CAL. FERTILITY INS.	2.0	30	33	30	3	3	0.10	0.10	0.20	0.18
CA-UCLA MEDICAL CENTER	5.0	0	0	0	0	0	-	-	-	-
CA-UCSF FERTILITY ASSOC.	2.0	4	4	4	0	2	0.00	0.50	0.50	0.50
CA-WHITTIER HOSPITAL	1.0	5	5	4	0	2	0.00	0.50	0.50	0.40
CO-REPRODUCTIVE GENETICS	0.0	0	0	0	0	0	-	-	-	-
CT-MT. SINAI HOSPITAL	1.7	7	7	5	0	0	0.00	0.00	0.00	0.00
CT-UCONN SCHOOL OF MED.	4.0	7	7	7	0	0	0.00	0.00	0.00	0.00
CT-YALE SCHOOL OF MED.	3.5	17	22	13	1	1	0.08	0.08	0.15	0.09
DC-COLUMBIA HOS FOR WOMEN	3.0	8	9	8	0	0	0.00	0.00	0.00	0.00
DC-GW UNIVERSITY IVF	3.0	14	14	14	0	5	0.00	0.36	0.36	0.36
FL-FERT CEN OF BOCA RATON	0.8	9	10	9	0	0	0.00	0.00	0.00	0.00
FL-FLORIDA FERTILITY	1.3	36	33	29	7	5	0.24	0.17	0.41	0.36
FL-HUMANA WOMEN'S HOSPIT.	2.3	21	26	19	1	6	0.05	0.32	0.37	0.27
FL-JACKSONVILLE MEM MED	1.8	14	20	10	5	1	0.50	0.10	0.60	0.30
FL-N.W. FLA. GULF BREEZE	1.3	32	37	27	3	5	0.11	0.19	0.30	0.22
FL-NW CENTER FOR INFERT.	1.4	16	16	15	2	0	0.13	0.00	0.13	0.13
FL-PARK AVE. WOMENS CENTR	0.3	1	1	1	0	0	0.00	0.00	0.00	0.00
FL-SAND LAKE IVF CENTER	2.1	6	6	6	0	1	0.00	0.17	0.17	0.17
GA-AUGUSTA REPROD. BIO.	0.0	0	0	0	0	0	-	-	-	-
GA-MEDICAL COLLEGE OF GA	2.5	4	4	2	0	0	0.00	0.00	0.00	0.00
GA-REPRODUCTIVE BIOLOGY	3.0	30	38	34	3	3	0.09	0.09	0.18	0.16
HI-KAHAI MEDICAL GROUP	3.0	5	6	6	0	0	0.00	0.00	0.00	0.00
HI-PACIFIC IVF INSTITUTE	0.0	0	0	0	0	0	-	-	-	-
IA-UNIVERSITY IOWA	1.4	30	44	35	2	10	0.06	0.29	0.34	0.27
IL-EVANSTON AND GLENBROOK	0.6	0	0	10	0	13	0.00	1.30	1.30	-
IL-MASONIC MEDICAL CENTER	1.0	33	48	31	5	5	0.16	0.16	0.32	0.21
IL-MICHAEL REESE HOSPITAL	2.0	55	56	56	4	4	0.07	0.07	0.14	0.14
IL-NORTHWESTERN MEMORIAL	3.0	43	49	40	13	8	0.32	0.20	0.52	0.43
IL-RUSH PRESB-ST. LUKE'S	1.4	76	76	64	7	6	0.11	0.09	0.20	0.17
IL-U. OF ILLINOIS MED. C.	2.3	2	2	2	0	0	0.00	0.00	0.00	0.00
IN-CENTER FOR REPROD.	1.3	2	2	1	0	0	0.00	0.00	0.00	0.00
IN-INDIANA UNIVERSITY	2.0	31	37	25	1	0	0.04	0.00	0.04	0.03
IN-PREGNANCY INITIATION	3.0	260	358	273	53	58	0.19	0.21	0.41	0.31
KS-REPROD. RESOUCE CENTER	2.3	59	94	70	10	18	0.14	0.26	0.40	0.30
KS-UNIV. KANSAS WICHITA	2.0	21	38	30	3	3	0.10	0.10	0.20	0.16
KY-FERTILITY INSTITUTE	2.3	24	32	32	4	1	0.13	0.03	0.16	0.16
KY-NORTON HOSPITAL	3.0	1	1	1	0	0	0.00	0.00	0.00	0.00

KY-UNIVERSITY OF KENTUCKY	2.7	14	19	14	2	1	0.14	0.07	0.21	0.16
LA-FERT INST NEW ORLEANS	4.0	179	228	163	36	30	0.22	0.18	0.40	0.29
MA-ALTANTICARE FERTILITY	0.0	0	0	0	0	0	-	-	-	-
MA-BRIGHAM & WOMEN'S HOS.	3.0	8	9	8	0	1	0.00	0.13	0.13	0.11
MA-NEW ENGLAND MED. CTR.	1.4	1	1	1	0	0	0.00	0.00	0.00	0.00
MD-UNIVERSITY OF MARYLAND	0.3	1	1	1	0	0	0.00	0.00	0.00	0.00
MD-WOMEN'S HOSPITAL CENTR	2.6	32	36	30	1	5	0.03	0.17	0.19	0.19
MI-BLODGETT MEMORIAL IVF	0.8	5	5	5	0	1	0.00	0.20	0.20	0.20
MI-HUTZEL HOSP./WAYNE ST.	3.2	1	1	1	0	0	0.00	0.00	0.00	0.00
MI-OAKWOOD HOSPITAL	0.0	0	0	1	0	0	0.00	0.00	0.00	-
MI-OCHI REPROD. ENDO.	1.6	77	131	109	12	33	0.11	0.30	0.41	0.34
MI-UNIV MI MEDICAL CENTER	3.0	4	4	4	0	0	0.00	0.00	0.00	0.00
MI-WILLIAM BEAUMONT HOSP.	2.1	6	6	6	0	1	0.00	0.17	0.17	0.17
MN-U. OF MINNESOTA	4.0	1	1	1	0	1	0.00	1.00	1.00	1.00
MO-WASHINGTON U. JEWISH	2.0	2	2	2	0	0	0.00	0.00	0.00	0.00
MS-U. MISS MEDICAL CENTER	4.0	4	4	2	0	0	0.00	0.00	0.00	0.00
NC-DUKE UNIVERSITY MED.	4.0	9	11	7	1	0	0.14	0.00	0.14	0.00
NC-NC MEMORIAL HOSPITAL	3.0	0	0	0	0	0	-	-	-	-
NC-NC REPROD. CENTER	0.0	0	0	0	0	0	-	-	-	-
NE-METHODIST HOSPITAL	1.4	1	1	1	0	0	0.00	0.00	0.00	0.00
NE-UNIVERSITY OF NEBRASKA	0.5	4	4	4	1	1	0.25	0.25	0.50	0.50
NH-DARTMOUTH-HITCHCOCK	0.0	0	0	0	0	0	-	-	-	-
NJ-ROBERT WOOD JOHNSON	3.5	13	13	13	0	0	0.00	0.00	0.00	0.00
NJ-UMDNJ NJ MED SCHOOL	1.6	1	1	1	0	1	0.00	1.00	1.00	1.00
NM-PRESBYTERIAN IVF	2.0	14	17	16	4	3	0.25	0.19	0.44	0.41
NV-NORTHERN NV FERTILITY	3.0	3	3	3	0	0	0.00	0.00	0.00	0.00
NY-ALBERT EINSTEIN COLL	2.0	33	42	36	1	5	0.03	0.14	0.17	0.14
NY-AUSTRALIA,UNITED HOSP.	0.0	0	0	0	0	0	-	-	-	-
NY-CHILDREN'S HOS. (BUFF)	3.0	10	12	12	0	0	0.00	0.00	0.00	0.00
NY-COLUMBIA PRESBYTERIAN	2.2	0	0	0	0	0	-	-	-	-
NY-LIFE PROGRAM	0.6	1	1	1	0	0	0.00	0.00	0.00	0.00
NY-MT. SINAI HOSPITAL	1.5	61	72	63	7	12	0.11	0.19	0.30	0.26
NY-NY HOSPITAL-CORNELL	2.0	19	31	21	3	2	0.14	0.10	0.24	0.16
NY-ST. LUKE'S ROOSEVELT	3.0	2	2	2	0	0	0.00	0.00	0.00	0.00
NY-U. OF ROCHESTER CARE	1.2	3	3	3	0	0	0.00	0.00	0.00	0.00
NY-WAYNE DECKER IVF PROGM	0.0	0	0	0	0	0	-	-	-	-
OH-AKRON CITY HOSPITAL	2.0	1	1	1	0	0	0.00	0.00	0.00	0.00
OH-BETHESDA FERTILITY	1.5	23	31	26	1	2	0.04	0.08	0.12	0.10
OH-CLEVELAND CLINIC FOUND	2.6	0	0	0	0	0	-	-	-	-
OH-JEWISH HOSP. OF CIN.	0.0	12	15	7	0	0	0.00	0.00	0.00	0.00
OH-MACDONALD HOSP.	4.0	0	0	0	0	0	-	-	-	-
OH-MIAMI VALLEY HOSPITAL	2.6	38	54	40	5	5	0.13	0.13	0.25	0.19
OH-MIDWEST REPROD. INST.	3.0	47	61	36	3	5	0.08	0.14	0.22	0.12
OH-MT. SINAI MED. CENTER	2.0	22	30	23	1	2	0.04	0.09	0.13	0.10
OH-RIVERSIDE REPROD. SERV	1.5	62	102	72	3	6	0.04	0.08	0.13	0.09
OH-UNIV REPROD. CENTER	3.0	63	81	66	4	1	0.06	0.02	0.08	0.06
OK-HENRY BENNETT FERTILTY	2.0	30	34	28	6	5	0.21	0.18	0.39	0.22
OK-HILLCREST FERTILITY	2.3	0	0	0	0	0	-	-	-	-
OR-EMANUEL HOSPITAL	1.3	2	2	2	0	0	0.00	0.00	0.00	0.00
OR-OR HEALTH SCIENCE UNIV	2.3	23	22	18	[illegible]	[illegible]	0.17	0.28	0.44	0.29
PA-ALBERT EINSTEIN MED	1.6	1	1	1	0	0	0.00	0.00	0.00	0.00
PA-ENDOCRINE HIST. ASSOC.	2.0	0	0	0	0	0	-	-	-	-
PA-FERT. CTR. ST. LUKES	3.0	59	79	52	6	5	0.12	0.10	0.21	0.14
PA-HOSPITAL OF U. PENN.	3.2	33	32	27	3	1	0.11	0.04	0.15	0.13
PA-MAGEE-WOMEN'S HOSPITAL	2.0	76	106	69	8	21	0.12	0.30	0.42	0.27
PA-PENN. REPRO. ASSOC.	3.7	127	152	120	8	25	0.07	0.21	0.27	0.20
PA-PITTSBURGH INSTITUTE	0.0	8	9	8	0	0	0.00	0.00	0.00	0.00
PA-WOMEN'S CLINIC LTD.	0.0	0	0	0	0	0	-	-	-	-
RI-WOMENS & INFANTS HOSP.	0.0	0	0	0	0	0	-	-	-	-
SC-MUSC IVF PROGRAM	0.0	0	0	0	0	0	-	-	-	-
SC-SOUTHEASTERN FERTILITY	3.0	64	73	38	1	11	0.03	0.28	0.31	0.16
TN-FAIR (MEMPHIS)	0.5	6	6	5	0	1	0.00	0.20	0.20	0.17
TN-VANDERBILT MED CTR.	3.0	14	16	14	4	2	0.29	0.14	0.43	0.38
TX-CENTER FOR REPRO. MED.	2.3	10	10	9	2	1	0.22	0.11	0.33	0.30
TX-FT. WORTH INFERT. CTR.	1.3	7	7	7	1	1	0.14	0.14	0.29	0.29
TX-HOUSTON REPRODUCTIVE	4.0	1	1	1	0	0	0.00	0.00	0.00	0.00

TX-J.D. BELUE, M.D.	2.2	7	12	7	1	0	0.14	0.00	0.14	0.08
TX-OB & GYN ASSOCIATES	4.0	87	104	91	7	8	0.08	0.09	0.16	0.14
TX-PRESB. HOSPITAL DALLAS	3.4	43	49	24	2	6	0.08	0.25	0.33	0.16
TX-SCOTT & WHITE CLINIC	0.2	2	3	2	0	1	0.00	0.50	0.50	0.33
TX-TRINITY IVF-ET PROGRAM	4.0	12	12	12	3	1	0.25	0.08	0.33	0.33
TX-U OF TEX-SW MED SCHOOL	3.0	2	2	2	0	0	0.00	0.00	0.00	0.00
TX-UNIV. OF TX GALVESTON	2.0	12	12	12	2	1	0.17	0.08	0.25	0.25
UT-UNIVERSITY OF UTAH	2.6	8	9	8	2	1	0.25	0.13	0.38	0.33
VA-HENRICO DRS HOSPITAL	2.9	17	17	16	1	4	0.06	0.25	0.31	0.29
VA-JONES INSTITUTE	3.0	2	2	2	0	1	0.00	0.50	0.50	0.50
VA-MEDICAL COLLEGE OF VA	0.3	1	1	1	0	0	0.00	0.00	0.00	0.00
VA-UNIVERSITY OF VIRGINIA	1.7	10	10	6	0	2	0.00	0.33	0.33	0.20
VT-UNIVERSITY OF VERMONT	2.7	0	0	0	0	0	-	-	-	-
WA-FERT CLIN PUGET SOUND	4.0	26	26	26	0	8	0.00	0.31	0.31	0.31
WA-RICE & ASSOCIATES	0.3	2	2	2	0	2	0.00	1.00	1.00	1.00
WA-SEATTLE FERT & GYN	3.4	54	57	47	10	11	0.21	0.23	0.45	0.37
WA-SEATTLE WOMEN'S CLINIC	1.9	5	6	4	1	0	0.25	0.00	0.25	0.17
WA-SWEDISH HOSP. MED. CTR	3.4	93	101	75	13	14	0.17	0.19	0.36	0.27
WA-UNIV. OF WASHINGTON	2.0	6	6	5	3	2	0.60	0.40	1.00	0.83
WI-APPLETON FAMILY FERT.	1.2	11	12	12	1	3	0.08	0.25	0.33	0.33
WI-UNIV. OF WISCONSIN	1.0	1	1	1	0	0	0.00	0.00	0.00	0.00
WV-W.VIRGINIA UNIVERSITY	1.0	32	50	35	5	4	0.14	0.11	0.26	0.18
TOTALS	289	3312	4193	3182	360	534	0.11	0.17	0.28	0.21
AVERAGES	2.68	30.67	38.82	29.46	3.33	4.94	0.11	0.17	0.28	0.21

- Year : years of operation prior to 12/31/88.
- Patients : number of women treated.
- Stim Cyc : (stimulation cycles) an attempt to produce eggs in a woman.
- Egg Rec : (egg recoveries) removal of eggs from a woman in order to fertilize them outside of her body.
- Live : number of live births.
- Cont Preg : continuing pregnancies that are ongoing but have not yet resulted in a live birth.
- L/ER : the percentage of egg recoveries that resulted in a live birth.
- C/ER : the percentage of continuing pregnancies that will result if all pregnancies result in a live birth.
- L+C/ER : the percentage of egg recoveries that resulted in a live birth or continuing pregnancy.
- L+C/SC : the percentage of stimulation cycles that resulted in a live birth or continuing pregnancy.

IVF/GIFT SURVEY

CLINIC NAME: Assisted Reproductive Technology (ART) Program
ADDRESS: 2006 Brookwood Medical Center Dr./#508
Birmingham, AL 35209

CONTACT PERSON: Director: Dr. Kathryn L. Honea (Assistant: Debbie Doonan)
PHONE NUMBER: 205-870-9784

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/2/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    - (a) Private X (located in community hospital office building-Hosp. OR used for GIFT, TET, etc.)
    - (b) Community hospital based ______
    - (c) University based ______
    - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
    - (a) Physicians 0
    - (b) Laboratory Scientists (PhDs) 0
    - (c) Nurses 3
    - (d) Embryo Lab Technicians/Technologists 3 (1 with Masters)
    - (e) Other Lab Technicians/Technologists 3
    - (f) Radiology (Ultrasound) Technicians 0
    - (g) Psychologists/Counselors 1
    - (h) Secretaries 1
    - (i) Other (specify) 1 receptionist, 2 financial coordinators, 1 administrator

7. How many years has your infertility clinic been in operation? 3 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 7/86 GIFT 7/88

TOTAL PATIENT #'S

9. How many different patients were stimulated?
1986: 124 1987 IVF 195 * 1988 IVF 150 **
GIFT 0 GIFT 8 (includes 1 TET) 373
*41 had cycles in 1986 **55 had cycles in 1987

10. How many stimulation cycles were performed?
1986: 161 1987 IVF 268 1988 IVF 219
GIFT 0 GIFT 8 (includes 1 TET) 648

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1986: 139 1987 227 1988 181 547

How many embryo transfer cycles were performed?
1986: 127 1987 196 1988 164 487

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 8 (includes 1 TET)

13. What were the number and percentage of patients on IRB approved research protocols?
1987 15 10 % 1988 56 37 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 123 63% 1988 IVF 87 58%
GIFT ___ 0 % GIFT ___ 0 %
(b) Endometriosis:
1987 IVF 35 18 % 1988 IVF 30 20%
GIFT ___ 0 % GIFT 2 20 %
(c) Male infertility:
1987 IVF 21 11% 1988 IVF 24 16%
GIFT ___ 0 % GIFT 4 40 %
(d) Unexplained infertility:
1987 IVF 10 5 % 1988 IVF 6 4 %
GIFT ___ 0 % GIFT 2 20 %
(e) Other (explain): sperm antibodies
1987 IVF 6 3 % 1988 IVF 3 2 %
GIFT ___ 0 % GIFT ___ 0 %

+ 70% had multiple diagnosis. These estimates based on primary diagnoses.

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 85 43.5% 1988 IVF 63 42 %
GIFT ___ N/A % GIFT ___ N/A %
(b) 31-35:
1987 IVF 67 34.4% 1988 IVF 55 35 %
GIFT ___ N/A % GIFT 5 62.5 %
(c) 36-40:
1987 IVF 43 22.1% 1988 IVF 29 21 %
GIFT ___ N/A % GIFT 2 25 %

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 3 2 %
GIFT 0 0 % GIFT 0 ___ %

(e) >45:
1987 IVF ___ ___ % 1988 IVF ___ ___ % N/A
GIFT ___ ___ % GIFT ___ ___ %

16. How many clinical pregnancies were produced?
1986: 26 1987 IVF 41 1988 IVF 29
0 GIFT 0 GIFT 1
TOTALS:
IVF: 96
GIFT: 1

17. How many women delivered live infants from IVF/GIFT?
1986 21 1987 IVF 34 1988 IVF 19 (as of 5/31/89)
0 GIFT 0 GIFT 0
TOTALS
IVF: 74
GIFT: 0
1986-Total live babies: 30; 1987-Total live babies: 41; 1988 live babies: 21 TOTAL BABIES 92

18. How many women have continuing pregnancies from IVF/GIFT?
1986: 0 1987 IVF 0 1988 IVF 8
0 GIFT 0 GIFT 1
TOTALS:
IVF: 8
GIFT: 1

19. How many ectopic pregnancies resulted? (not included in #16)
1986: 2 1987 IVF 5 1988 IVF 1
0 GIFT 0 GIFT 0
TOTALS:
IVF: 8
GIFT: 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 3% Triplets 1/34 - 7/34 All delivered
GIFT ___ ___ % ___

1988 IVF 1 1 % Delivered: Twins 2/27, Expected: 1/27
GIFT ___ ___ % ___

21. What are the qualifications of the director of the embryo laboratory? Director: Dr. Kathryn L. Honea: M.S. in Physiology and Biophysics M.D., OB/GYN residency, Fellowship in Reproductive Endocrinology. Acting supervisor: Debbie Merryman, A.S., 5 yrs. experience as IVF Technician.

22. Who supervises the laboratory director? Director of Program is Lab Director as well (Dr. Kathryn L. Honea)

23. Does the clinic participate in an external laboratory proficiency testing program? Yes - radioimmunoassay
If the answer is yes, please specify which program.
RIA: Beginning CAP, none available for embryology.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? yes

27. Does the clinic train individuals in IVF or GIFT? _____ If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians _____
    (b) Laboratory scientists (PhDs) _____
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _____
    (e) Other (explain) _____

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes, since 1987

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?

(a) Physicians 4
(b) Laboratory scientists (PhDs) ______
(c) Embryo laboratory technicians/technologists 2
(d) Nurses 2
(e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

In mid-1987 our program changed to 3 embryo transfers as first choice for first cycle. We analyzed our data and found we could significantly decrease multiple births by encouraging 3 embryo transfers for the initial cycle only. Pregnancy rates that cycle were still greater than 25% clinical pregnancy per transfer, but there were no quadruplets and less than 1% triplets. Patients can receive up to 4 embryos on subsequent cycles.

Clinical pregnancy rates per embryo transfer are related to number of embryos transferred. Three to four embryo transfers have ≥ 30% rate combined.

In mid-1988 our program changed from IVF Australia to ART Program which is owned and managed by Dr. Kathryn L. Honea.

After changing to Lupron stimulation for all patients, cancellation rates in cycles have decreased to 5/65 (8%) with overall clinical pregnancy rate of - 13/53 (25%) per transfer, and 13/60 (22%) per retrieval (includes 6 patients with severe male factor and no fertilization.).

GIFT/TET began with patients who needed laparoscopy for other reasons - GIFT was offered in that context. No pregnancies in male factor group; these patients also had very poor fertilization on excess eggs. We are opening this program for patients who have not obtained pregnancies with Pergonal or IUI.

This program is a member of the NIH study entitled, "Health Surveillance of Women Treated for Infertility by In Vitro Fertilization."

IVF/GIFT SURVEY

CLINIC NAME: [University of Alabama] at Birmingham IVF/GIFT Program
ADDRESS: Department of Obstetrics & Gynecology
UAB Station
Birmingham, AL 35294

CONTACT PERSON: Elisabeth McElroy, R.N.
PHONE NUMBER: (205) 934-7121

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 6/30/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    - (a) Private ______
    - (b) Community hospital based x
    - (c) University based X
    - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 4

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
    - (a) Physicians 4 (Anesthesiologists)
    - (b) Laboratory Scientists (PhDs) 1
    - (c) Nurses 10 (4 Clinic: 3 OR: 3 Same Day Surgery)
    - (d) Embryo Lab Technicians/Technologists 2
    - (e) Other Lab Technicians/Technologists 2
    - (f) Radiology (Ultrasound) Technicians 0
    - (g) Psychologists/Counselors 0
    - (h) Secretaries 2
    - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 4

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1984 GIFT 1987

9. How many different patients were stimulated?
1987 IVF 39 1988 IVF 36
GIFT 6 GIFT 24

10. How many stimulation cycles were performed?
1987 IVF 53 1988 IVF 39
GIFT 8 GIFT 35

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 30 1988 21

How many embryo transfer cycles were performed?
1987 28 1988 20

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 4 1988 22

13. What were the number and percentage of patients on IRB approved research protocols?
1987 45 100% 1988 60 100 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 25 64% 1988 IVF 25 69 %
GIFT 1 17 % GIFT 1 4 %
(b) Endometriosis:
1987 IVF 9 23% 1988 IVF 5 14 %
GIFT 2 31 % GIFT 11 46 %
(c) Male infertility:
1987 IVF 3 8 % 1988 IVF 4 11 %
GIFT 1 17 % GIFT 9 38 %
(d) Unexplained infertility:
1987 IVF 2 5 % 1988 IVF 1 3 %
GIFT 2 33 % GIFT 8 33 %
(e) Other (explain): Sperm Antibodies
1987 IVF 4 10 % 1988 IVF 2 6 %
GIFT 2 33 % GIFT 2 8 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 8 21% 1988 IVF 13 36 %
GIFT 2 29% GIFT 7 29 %
(b) 31-35:
1987 IVF 24 61 % 1988 IVF 7 19%
GIFT 4 71 % GIFT 10 42%
(c) 36-40:
1987 IVF 5 13 % 1988 IVF 15 42 %
GIFT 0 0 % GIFT 7 29 %

(d) 41-45:
1987 IVF 2 5 % 1988 IVF 1 1 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 2 1988 IVF 5
GIFT 2 GIFT 7

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 1 1988 IVF (Not Available)
GIFT 1 GIFT (Not Available)

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF (*) 1988 IVF 4
GIFT (*) GIFT 4
*Not Applicable

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 2

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 % ______
GIFT 1 100 % 1 Twins

1988 IVF 0 0 % ______
GIFT 0 0 % ______

21. What are the qualifications of the director of the embryo laboratory? M.D. Reproductive Endocrinologist

22. Who supervises the laboratory director? Richard E. Blackwell, Ph.D., M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
College of American Pathologists

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? ____Yes____

27. Does the clinic train individuals in IVF or GIFT? __No__
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

1. Continuing pregnancies also established with pronuclear stage embryo transfer (PROST) procedure.

2. Egg retrievals done by transvaginal ultrasound guided technique or by laparoscopy, with local, epidural, [illegible] or general anesthesia available.

UNIVERSITY S. ALABAMA

IVF/GIFT SURVEY

CLINIC NAME: IVF/GIFT
ADDRESS: Div. Reproductive Endocrinology,Dept. OB-GYN
University of South Alabama
CC/CB
Mobile, AL 36688
CONTACT PERSON: Sezer Aksel, M.D.
PHONE NUMBER: (205)460-7173

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Sept. 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ____
   - (b) Community hospital based ____
   - (c) University based X
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 4

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 0

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 1
   - (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? 1.25

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 6/4/87 GIFT 10/15/87

9. How many different patients were stimulated?
1987 IVF 14 1988 IVF 18
GIFT 1 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 17 1988 IVF 22
GIFT 1 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 17 1988 21

How many embryo transfer cycles were performed?
1987 14 1988 16

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 15 100% 1988 19 100%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 4 27% 1988 IVF 4 21%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 1 7% 1988 IVF 4 21%
GIFT ___ ___% GIFT 1 6%
(c) Male infertility:
1987 IVF 5 33% 1988 IVF 5 26%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF 4 27% 1988 IVF 4 21%
GIFT 1 6% GIFT ___ ___%
(e) Other (explain): POF
1987 IVF ___ ___% 1988 IVF 1 5%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 1 5% 1988 IVF 1 5%
GIFT 0 0% GIFT 0 0%
(b) 31-35:
1987 IVF 14 67% 1988 IVF 8 42%
GIFT 2 10% GIFT 0 0%
(c) 36-40:
1987 IVF 4 19% 1988 IVF 9 47%
GIFT 0 0% GIFT 1 5%

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 2 1988 IVF 2
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___% ______________________
GIFT 0 ___% ______________________

1988 IVF 0 ___% ______________________
GIFT 0 ___% ______________________

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Reproductive Physiology

22. Who supervises the laboratory director? IVF Director

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
IVF Program, Univ. North Carolina, Chapel Hill, NC

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? not yet

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 1 (Fellow-Reproductive Endocrinology)
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 0
    (d) Nurses 0
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

This is a new clinic in this area with a small patient load which attracted women in the older age group, some of whom had previously failed IVF trials. Four clinical pregnancies have been achieved since the start. Two abortions occurred in the 1st trimester, and 2 in the 2nd, at 13½ and 22 weeks gestation. Chromosome analysis of the two mid-trimester abortuses were normal.

IVF/GIFT SURVEY

CLINIC NAME: Arizona Center For Fertility Studies
ADDRESS: 4614 E. Shea Blvd.
Suite D-260
Phoenix, AZ 85028

CONTACT PERSON: Jay S. Nemiro, M.D.
PHONE NUMBER: (602) 996-7896

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 9/14/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ____
   - (b) Community hospital based X
   - (c) University based ____
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? One (See Note 4)

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? One

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) One
   - (c) Nurses Two
   - (d) Embryo Lab Technicians/Technologists 0
   - (e) Other Lab Technicians/Technologists One
   - (f) Radiology (Ultrasound) Technicians Two
   - (g) Psychologists/Counselors One
   - (h) Secretaries Two
   - (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? Seven

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF May, 1984 GIFT February, 1985

9. How many different patients were stimulated? *(See Note 9.)*
1987 IVF ______ [illegible] 1988 IVF [illegible]
GIFT ______ 1988 GIFT [illegible]

10. How many stimulation cycles were performed? *(See Note 10.)*
1987 IVF [illegible] 1988 IVF [illegible]
GIFT 864 1988 GIFT 367

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 Seven 1988 five

How many embryo transfer cycles were performed?
1987 Seven 1988 five

12. How many GIFT procedures (attempted egg recoveries) were performed? *(See Note 12.)*
1987 188 1988 138

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 — % 1988 0 — %

14. What were the number and percentage of patients treated for:
(a) Tubal factor: *(See Note 14.)*
1987 IVF 7 100% 1988 IVF 4 80%
GIFT 19 10% GIFT 11 8%
(b) Endometriosis:
1987 IVF — — % 1988 IVF 0 — %
GIFT 39 21% GIFT 25 18%
(c) Male infertility:
1987 IVF — — % 1988 IVF 1 20%
GIFT 8 4% GIFT 20 15%
(d) Unexplained infertility:
1987 IVF — — % 1988 IVF 0 — %
GIFT 35 19% GIFT 25 18%
(e) Other (explain) ______
1987 IVF — — % 1988 IVF 0 — %
GIFT 87 46% GIFT 57 41%

15. What were the number and percentage of patients in the following age groups:
(a) [illegible]
1987 IVF 2 29% 1988 IVF 1 20%
GIFT 69 37% GIFT 39 28%
(b) 31-35:
1987 IVF 2 29% 1988 IVF 1 20%
GIFT 63 34% GIFT 51 37%
(c) 36-40:
1987 IVF 3 42% 1988 IVF 1 20%
GIFT 45 23% GIFT 39 28%

(d) 41-45:
1987 IVF 0 — % 1988 IVF 1 20%
GIFT 11 6 % GIFT 8 6 %

(e) >45:
1987 IVF 0 — % 1988 IVF 1 20%
GIFT 0 — % GIFT 1 1 %

16. How many clinical pregnancies were produced? (See Note 16.)
1987 IVF 0 1988 IVF 0
GIFT 61 GIFT 53

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 45 GIFT 19

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF — 1988 IVF — (See Note 18.)
GIFT — GIFT 22

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 2 GIFT 5

20. What were the number, percentage of all births, and plurality, of multipie births?
1987 IVF — — %
GIFT 10 22 % 6: Twin, 4: Triplet

1988 IVF — %
GIFT 8 42 % 5: Twin, 2: Triplet, 1: Quad.

21. What are the qualifications of the director of the embryo laboratory? Ph.D. See Attached C.V.

22. Who supervises the laboratory director? Self-Supervised

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
JCAH

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No. Intend to apply.

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 3
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 0
    (d) Nurses two
    (e) Other (explain) One lab tech.

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

(See Attached Comments.)

IVF/GIFT SURVEY

ARIZONA CENTER FOR FERTILITY STUDIES

NOTES AND COMMENTS FOR SURVEY

Note 4. Dr. Nemiro carried out his Fellowship in Reproductive Endocrinology and Infertility at Georgetown University during 1980-1981.

Note 9. Unfortunately, we are unable to provide at this time data on number of individual patients who began stimulation cycles. We currently are organizing those data, and if it is possible, we shall send them when available. Please see Comments section regarding our philosophy on stimulation cycles.

Note 10. For the small number of IVF procedures we performed, our data are not accurate for numbers of stimulation cycles. Our usual cancellation rate for tubal transfer stimulations is approximately fifty percent. I assume that figure is quite close for the IVF stimulations; and this translates to approximately 14 IVF stimulations for 1987 and 10 for 1988.

Note 12. The data provided include only cycles in which tubal transfer (GIFT) was actually performed. The data base from which these numbers were derived has intentionally excluded cycles which were cancelled for reasons of inaccessible ovaries or fallopian tubes. The incidence of such cancellations in our program is approximately five percent. In nearly all such cancelled cases, the patients were aware of the risk of cancellation because of suspected adhesions.

Note 14. The "Other" category for 1987 included pelvic adhesions (42 cycles), anovuation (19 cycles), cervical factor (17 cycles), immunologic infertility (2 cycles), luteal phase defect (4 cycles) and premature menopause (3 cycles). The "Other" category for 1988 included pelvic adhesions (39 cycles), anovulation (6 cycles), cervical factor (6 cycles), luteal phase defect (2 cycles) and premature menopause (4 cycles). Obviously, our data for this section relate to total cycles and not to different patients.

Note 16. The definition of clinical pregnancy in our program is as follows: The ultrasonographic observation of a gestational sac in the uterus at four and one half weeks following tubal transfer or the presence of an ectopic pregnancy.

Note 18. All ongoing pregnancies for the 1987 tubal transfers have been completed and the babies born as of this date. Therefore, we show no continuing 1987 pregnancies.

IVF/GIFT SURVEY

ARIZONA CENTER FOR FERTILITY STUDIES

COMMENTS (ITEM 28 OF SURVEY FORM)

As indicated in the survey, our program is highly selective of stimulation cycles taken to surgery. We cancel cycles which exhibit evidence of cystic follicular development, excessive follicular atresia, those with low estrogen levels and those with high luteinizing hormone levels. Therefore our patients are told at the beginning that it is likely they shall require more than one, and perhaps several stimulation cycles to qualify for oocyte retrieval and tubal transfer. Our annual number of stimulation cycles therefore is intentionally very high as compared with the actual number of tubal transfer cycles performed. We feel that, generally speaking, only those cycles which culminate in tubal transfer expose the patient to pregnancy. Our selection of appropriate stimulation cycles also is justified on the basis of decreasing the exposure of patients to the risks and cost of surgery in circumstances where our experience demonstrates a reduced probability for ongoing pregnancy.

We prefer to perform tubal transfer (GIFT) on every qualified infertile patient who has failed other, conventional treatments and who exhibits clear evidence of at least one patent and accessible fallopian tube. It is our experience that very few patients fail to qualify. Our recommendation is that IVF-ET should never be performed if a patient is qualified for tubal transfer (GIFT). Our recommendation is based on the lower expense of tubal transfer and the substantially higher success rate for tubal transfer relative to IVF-ET in our experience. Certainly if a patient would be threatened by general anesthesia, then perhaps the only alternative would be to perform nonsurgical needle aspiration of oocytes for IVF-ET. However, we suspect that circumstance is exceptionally rare.

From analysis of repeat cycles for individual patients in our program, we can predict very high cumulative probability for continuing pregnancy and birth (in the range of 70-80%) for patients who can commit themselves to three attempts at tubal transfer. Our calculations of this high success probability are based on a patient population of 431 patients and include "per patient" incidences of continuing pregnancy for a single attempt (34%) for the second attempt (32%) and for the third attempt (52%). The accumulated number of patients who should achieve continuing pregnancy in this series is calculated at 338 or 78% of the 431 beginning patients.

We have added to our tubal transfer program the capability of providing donor oocytes to patients who continually fail to produce normal oocytes on their own or who exhibit premature menopause. This procedure has been highly successful and often employs a natural cycle for the recipient patient. In addition our program makes use of "simulated cycles" by treating noncycling patients with estrogen to provide an adequate follicular phase for transfer of donor oocytes. Our program also has the facilities to cryopreserve both sperm and unfertilized oocytes for use in future cycles of tubal transfer or IVF-ET.

Since the ending date (August 11, 1988) for the data incorporated into the enclosed survey, we have performed an additional 60 cycles of tubal transfer. Of those cycles (55) which have progressed far enough to assess pregnancy, there have been 21 (38%) clinical pregnancies and 20 (36%) of these are ongoing as of December 16, 1988.

By way of summary for our tubal transfer (GIFT) program: We performed 188 tubal transfers in 1987, and obtained 61 clinical pregnancies (32.5% of transfers) and 45 pregnancies were delivered (23.5% of transfers). To date (December 16, 1988) in 1988, we have performed 193 transfers (including those for which pregnancy data are available), and have obtained 74 clinical pregnancies (38.3% of transfers) and 61 pregnancies have delivered or are ongoing (31.6% of transfers).

We provide also a general summary for our tubal transfer (GIFT) program since it began in February, 1985. We have performed 660 tubal transfers up to December 16, 1988. Of the total transfers, 280 (42%) resulted in elevated hCG (biochemical pregnancy), 216 (32.7%) produced clinical pregnancies and 168 (25.5% of transfers) produced births or are ongoing. To date these transfers have produced 174 babies born and the ongoing pregnancies are expected to produce an additional 63 babies.

IVF/GIFT SURVEY

CLINIC NAME: ARIZONA FERTILITY INSTITUTE
ADDRESS: 2850 N. 24th Street
Suite 500-A
Phoenix, AZ 85008

CONTACT PERSON: H. Randall Craig, M. D.
PHONE NUMBER: (602) 468-3840

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Dec., 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ______
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 4
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 3
   - (f) Radiology (Ultrasound) Technicians 4
   - (g) Psychologists/Counselors 2
   - (h) Secretaries 4
   - (i) Other (specify) 14 Insurance, Billing, MBA Business Dir., Medical Records, Computer Techs.

7. How many years has your infertility clinic been in operation? 4 ½ yrs. IVF, 25 yrs. infertility.

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1984 GIFT 1985

9. How many different patients were stimulated?
1987 IVF 59 1988 IVF 88
GIFT 9 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 81 1988 IVF 117
GIFT 12 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 72 1988 108

How many embryo transfer cycles were performed?
1987 54 1988 97

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 8 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF 39 44 %
GIFT ___ ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 6 7 %
GIFT ___ ___% GIFT 0 ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 12 14 %
GIFT ___ ___% GIFT 0 ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF 1 1 %
GIFT ___ ___% GIFT 0 ___%
(e) Other (explain): Ovarian hypofunction, autoimmune
1987 IVF ___ ___% 1988 IVF 30 34 % disease
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF 15 17 %
GIFT ___ ___% GIFT 0 ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF 43 49 %
GIFT ___ ___% GIFT 0 ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF 24 27 %
GIFT ___ ___% GIFT 0 ___%

Computer data for diagnosis and age breakdown are available beginning Jan., 1988. Data for 1987 not available until computer file is updated.

(d) 41-45:
1987 IVF ___ ___% 1988 IVF 6 7 %
GIFT ___ ___% GIFT 0 ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF 0 0 %
GIFT ___ ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF 15 1988 IVF 15
GIFT 1 GIFT N.A.

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 12 1988 IVF 4
GIFT 1 GIFT N.A.

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF - 1988 IVF 8
GIFT - GIFT N.A.

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 2
GIFT 0 GIFT N.A.

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 5 42 % 2 sets twins, 3 sets triplets
GIFT 0 ___% ___

1988 IVF 1 7 % 1 set twins
GIFT 0 ___% ___

21. What are the qualifications of the director of the embryo laboratory? B.Vet Sc., PhD Embryology, 11 yrs. experience in Reproductive Biology, 8 yrs. experience in In Vitro Fertilization

22. Who supervises the laboratory director? Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? No. CAP application pending
If the answer is yes, please specify which program.
CAP certification pending

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 1
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 2
    (d) Nurses 3
    (e) Other (explain) 0

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. These comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Arizona Fertility Institute has an academic affiliation with Maricopa County Teaching Hospital

The physicians and embryologist are actively engaged in basic science and clinical research with interests in platelet activating factor and atrial natriuretic peptide in reproductive systems along with innovative high tech reproductive procedures and cryopreservation.

IVF patients receive HCG luteal supoort, so two serum pregnancy tests demonstrating increasing levels of HCG are required to diagnose pregnancy.

The success rate for frozen embryo transfers for 1988 is:

4 clinical pregnancies/15 frozen embryo transfer procedures = 26%

Couples enrolled in the IVF and GIFT programs refrain from intercourse during these cycles to prevent possible success rate interference from natural pregnancies. IVF & GIFT programs have no age restrictions.

I strongly urge the Subcommittee to site visit IVF and GIFT programs to verify the data submitted by this survey.

IVF/GIFT SURVEY

CLINIC NAME: The Reproductive Institute of Tucson
ADDRESS: 1200 N. El Dorado Place
Bldg G, Ste 700
Tucson, AZ 85715

CONTACT PERSON: Wayne A. Hudak, M.D.
PHONE NUMBER: 602-290-8818

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 15Nov88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based ______
   - (d) Other (explain) Private with affiliation to University of Arizona Medical Technology Program

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? None on staff but with consulting endocrinologist

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   - (a) Physicians 2 (Urology & GYN)
   - (b) Laboratory Scientists (PhDs) 4
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 3
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 2
   - (i) Other (specify) 2 business office/finance

7. How many years has your infertility clinic been in operation? 2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1986 GIFT 1986

9. How many different patients were stimulated?
1987 IVF 7 1988 IVF 9
GIFT 10 GIFT 5

10. How many stimulation cycles were performed?
1987 IVF 8 1988 IVF 10
GIFT 10 GIFT 6

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 7 1988 9

How many embryo transfer cycles were performed?
1987 7 1988 7

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 10 1988 5

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:

Most couples that undertake IVF/GIFT in our facility have multiple indications for IVF/GIFT. These numbers are a total of indications, usually 2 or 3 per couple.

(a) Tubal factor:
1987 IVF 7 88 % 1988 IVF 6 60 %
GIFT 3 30 % GIFT 3 60 %
(b) Endometriosis:
1987 IVF 5 62 % 1988 IVF 3 30 %
GIFT 8 80 % GIFT 5 100%
(c) Male infertility:
1987 IVF 2 25 % 1988 IVF 4 40 %
GIFT 2 20 % GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %
(e) Other (explain): severe cervical stenosis
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 2 20% GIFT 0 0 %

15. What were the number and percentage of patients in the following age groups: patients counted only once if multiple cycles in the year
(a) <31:
1987 IVF 0 0 % 1988 IVF 1 10 %
GIFT 0 0 % GIFT 0 0 %
(b) 31-35:
1987 IVF 5 62 % 1988 IVF 2 20 %
GIFT 6 60 % GIFT 2 40 %
(c) 36-40:
1987 IVF 3 38 % 1988 IVF 5 50 %
GIFT 4 40 % GIFT 3 60 %

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 1 10 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 2 1988 IVF 2
GIFT 4 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 2 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT n/a GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% no multiple birth
GIFT ___ ___% from
IVF or GIFT
1988 IVF ___ ___% ___
GIFT ___ ___% ___

21. What are the qualifications of the director of the embryo laboratory? PhD Immunology/Cell Biology, 15 years of experience in tissue culture and cryopreservation techniques

22. Who supervises the laboratory director? State of Arizona, as laboratory is a state licensed facility.

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
1) College of American Pathologist 2) Charles River Professional Services
Cryotech Zcell

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 1 10 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 2 1988 IVF 2
GIFT 4 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 2 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT n/a GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% no multiple birth
GIFT ___ ___% from
IVF or GIFT
1988 IVF ___ ___%
GIFT ___ ___%

21. What are the qualifications of the director of the embryo laboratory? PhD Immunology/Cell Biology, 15 years of experience in tissue culture and cryopreservation techniques

22. Who supervises the laboratory director? State of Arizona, as laboratory is a state licensed facility.

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
1) College of American Pathologist 2) Charles River Professional Services
Cryotech Zcell

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ______
    (b) Laboratory scientists (PhDs) 2
    (c) Embryo laboratory technicians/technologists 3
    (d) Nurses 2
    (e) Other (explain) All University of Arizona Medical Technology students rotate thru gamete laboratory

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The focus of our program is to integrate assisted reproductive technologies -A.R.T.- into the diagnosis, as well as therapy, of our patients. Our philosophy is to use IVF/GIFT procedures as little as possible but use their ovulation induction and monitoring techniques to facilitate controlled hyperstimulation with intrauterine insemination in attempts for pregnancy. The majority of our patients become pregnant in several cycles using these protocols and consequently are spared the invasiveness and expense of GIFT and/or IVF. An analysis of our data over the last 18 months has shown pregnancy rates of up to 35% per cycle in couples who would be categorized as GIFT/IVF candidates. Only those couples who fail controlled hyperstimulation or have an absolute indication for In Vitro Fertilization, (eg., bilaterally blocked fallopian tubes), go on to appropriate IVF and/or GIFT procedures.

When laparoscopy is undertaken for GIFT/IVF, the scope of the procedure includes operative laparoscopy to affect adhesiolysis and laser vaporization of endometriosis. The laparoscopy is viewed not only as a means to implement GIFT or IVF but as an opportunity to optimize the pelvic structure for conception. By using concomitant operative laparoscopy, five patients who failed to become pregnant with their GIFT procedure in 1987/88 have subsequently conceived using follow-up controlled hyperstimulation with IUI.

Before any A.R.T. are undertaken, be it hyperstimulation with IUI, GIFT, or IVF, the probable success rates of these procedures are thoroughly discussed in light of each couple's fertility factors. The endpoint of fertility management is delineated, and the patients are encouraged to consider the expected success rates of A.R.T. procedures in their situation versus other applicable options such as donor insemination or adoption. If A.R.T. fail in their situation, it is seen as a positive step toward these other options for family planning. Many of our patients with our encouragement will elect to invest their time, effort, and financial resources into options such as adoption rather then proceed at that time with further fertility management.

IVF/GIFT SURVEY

CLINIC NAME: Southwest Fertility Center, Ltd.
ADDRESS: 3125 N. 32nd St, Ste #200
Phoenix, AZ.
85018

CONTACT PERSON: Sujatha Gunnala, M.D.
PHONE NUMBER: 602-956-7481

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12-5-88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1 (Same)

6. How many other professionals participate in your clinic?
   - (a) Physicians 1 (same)
   - (b) Laboratory Scientists (PhDs) Currently negotiating
   - (c) Nurses 2 (1 R.N., 1 certified nurse practitioner)
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists ________
   - (f) Radiology (Ultrasound) Technicians 1 (R.N.) → nurse practitioner
   - (g) Psychologists/Counselors 1 (on-call)
   - (h) Secretaries 3
   - (i) Other (specify) Medical Assitant - 1
     Nurse Anesthetist (on-call) - 1

7. How many years has your infertility clinic been in operation? 8

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 6/88 GIFT 11/86

9. How many different patients were stimulated?
1987 IVF 0 1988 IVF 4
GIFT 25 GIFT 33

10. How many stimulation cycles were performed?
1987 IVF 0 1988 IVF 6
GIFT 31 GIFT 41

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 0 1988 4

How many embryo transfer cycles were performed?
1987 0 1988 3

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 16 1988 21

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0 % 1988 ___ 0 %

14. What were the number and percentage of patients treated for:

(a) Tubal factor:
1987 IVF — % 1988 IVF 4 100 %
GIFT 0 0 % GIFT 0 0 %

(b) Endometriosis: (Stage III + IV & mod. + more)
1987 IVF — % 1988 IVF 0 0 %
GIFT 5 31 % GIFT 6 29 %

(c) Male infertility:
1987 IVF — % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 2 9 % (retrograde ejaculation; oligospermia)

(d) Unexplained infertility:
1987 IVF — % 1988 IVF 0 0 %
GIFT 6 37 % GIFT 3 14 %

(e) Other (explain): Oligoanovulation, PCO; multiple factors; pelvic adhesions
1987 IVF — % 1988 IVF 0 0 %
GIFT 5 31 % GIFT 10 48 %

15. What were the number and percentage of patients in the following age groups: (of those who went to surgery);

(a) <31:
1987 IVF — % 1988 IVF 1 25 %
GIFT 7 44 % GIFT 10 48 %

(b) 31-35:
1987 IVF — % 1988 IVF 3 75 %
GIFT 4 25 % GIFT 11 52 %

(c) 36-40:
1987 IVF — % 1988 IVF 0 0 %
GIFT 5 31 % GIFT 0 0 %

(d) 41-45:
1987 IVF — % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF — % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF — 1988 IVF 1
GIFT 3 * GIFT 6
*(the 2 most recent patients are as yet untested for pregnancy)

17. How many women delivered live infants from IVF/GIFT?
1987 IVF — 1988 IVF 0
GIFT 3 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF — 1988 IVF 1
GIFT all delivered GIFT 3

19. How many ectopic pregnancies resulted?
1987 IVF — 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF — % 2 sets twins
GIFT 2 · 66% %
1988 IVF 0 %
GIFT 0 %

21. What are the qualifications of the director of the embryo laboratory? B.S. Zoology from UNC 1983. Four years IVF Lab Coordinator Duke University Med. Center. One year director at Southwest Fertility

22. Who supervises the laboratory director? M.D. director

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Currently applying

27. Does the clinic train individuals in IVF or GIFT? NO
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ______
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ______
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

As a relatively small private practice, we employ the use of GIFT and IVF rather conservatively: For IVF, a patient must have definite tubal dysfunction or occlusion.

Before taking a patient to GIFT, we usually attempt several cycles of intrauterine inseminations, with or without controlled ovarian stimulation. Indeed, many of our patients have conceived in this manner without having to resort to surgery.

Our patient population varies considerably in terms of age, duration of infertility, and causal factors. A majority of them come to us as referrals from local gynecologists who have tried various treatments. As such, we tend to see many complicated cases.

Our current success rates are:

GIFT: conception rate (per cycle) = 42.8% (includes chemical pregnancies)
clinical pregnancy rate = 25.7 %
on-going pregnancy rate = 20.0%

IVF: on-going pregnancy rate = 33 % → the small number of procedures done thus far must be taken into consideration

IVF/GIFT SURVEY

CLINIC NAME: Alta Bates Hospital
ADDRESS: In Vitro Fertilization Program
3001 Colby Street
Berkeley, CA 94705

CONTACT PERSON: Ryszard J. Chetkowski, M.D. Director
PHONE NUMBER: (415) 540-1416

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 10/31/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based X
   (c) University based ______
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? One

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? One (same as in #4 above)

6. How many other professionals participate in your clinic?
   (a) Physicians None
   (b) Laboratory Scientists (PhDs) One
   (c) Nurses Two
   (d) Embryo Lab Technicians/Technologists One
   (e) Other Lab Technicians/Technologists None
   (f) Radiology (Ultrasound) Technicians None
   (g) Psychologists/Counselors None
   (h) Secretaries One
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 4 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1984 GIFT 1986

9. How many different patients were stimulated?
1987 IVF 113 1988 IVF 123
GIFT 2 GIFT 2

10. How many stimulation cycles were performed?
1987 IVF 137 1988 IVF 141
GIFT 2 GIFT 2

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 109 1988 114

How many embryo transfer cycles were performed?
1987 106 1988 109

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 2 1988 2

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0 % 1988 ___ 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 80 73% 1988 IVF 80 70%
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 17 16% 1988 IVF 11 10%
GIFT 0 0 % GIFT 1 50 %
(c) Male infertility:
1987 IVF 3 3 % 1988 IVF 8 7 %
GIFT 0 0 % GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 9 8 % 1988 IVF 15 13%
GIFT 2 100% GIFT 1 50%
(e) Other (explain): ___
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 5 5% 1988 IVF 12 11%
GIFT 0 0 % GIFT 0 0 %
(b) 31-35:
1987 IVF 35 32% 1988 IVF 26 23%
GIFT 0 0 % GIFT 0 0 %
(c) 36-40:
1987 IVF 59 54% 1988 IVF 63 55%
GIFT 1 50 % GIFT 1 50 %

(d) 41-45:
1987 IVF 10 9 % 1988 IVF 13 11 %
GIFT 1 50 % GIFT 1 50 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 29 1988 IVF 34
GIFT 1 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 17 1988 IVF 13
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 14
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 3
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 10 59% 6 sets of twins, 4 sets of triplets
GIFT 0 0 %

1988 IVF 5 38 % 5 sets of twins
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in reproductive biology, 5 years of experience in IVF programs

22. Who supervises the laboratory director? R. J. Chetkowski, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ______
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ______
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

In the Alta Bates Hospital In Vitro Fertilization Program the age limit for women is the 43rd birthday. The treatment results are tabulated according to the patients' age with the 40th birthday as the dividing point, and prospective patients are counselled accordingly.

From January 1, 1987 to October 31, 1988, 172 and 51 egg retrievals were performed resulting in 56 and 7 clinical pregnancies in women under 40 years and aged 40-42, respectively. The corresponding clinical pregnancy rates per retrieval were 32% and 14%. The ongoing intrauterine pregnancy rates per retrieval in the two age groups were 23% and 10%.

Alta Bates is a non-profit community hospital which has provided quality medical care to East Bay residents since 1905. With nearly 4,000 births per year, Alta Bates Hospital has one of the largest and most progressive departments of obstetrics and gynecology in Northern California. The In Vitro Fertilization (IVF) Program is a natural outgrowth of this comprehensive service and was developed to meet a growing community need.

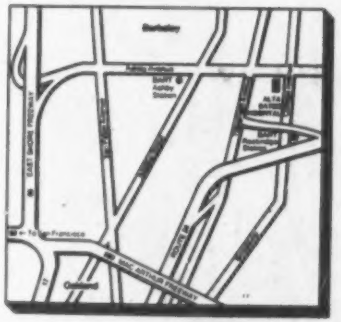
Infertility has reached near-epidemic proportions in the 1980s, profoundly affecting one of every six couples. Since the birth of the first "test tube baby" in England in 1978, IVF has moved from the realm of scientific research into the domain of successful medical procedures, offering new hope to many childless couples.

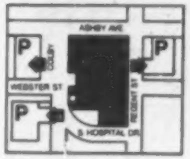
Who is a candidate for IVF?

IVF is the technique of fertilizing a woman's eggs in the laboratory for the treatment of infertility. While it was designed primarily for couples with tubal disease, IVF has been applied with equal success to infertility due to endometriosis, poor cervical mucus and unexplained factors. Recently the technique has been extended to infertility resulting from a low sperm count, but the success rate in these cases is often lower. A variant of IVF, the GIFT procedure, is also available to women with normal fallopian tubes.

The age limit for women is 42 years, because the procedure is much less successful in older women. In general, IVF is employed after other methods of treatment have been tried and proven unsuccessful.

Directions to Alta Bates Hospital





P = Parking

ALTA
BATES

Alta Bates Hospital
3001 Colby Street
Berkeley, California 94705
(415) 540-0337

11/87

ALTA
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In Vitro Fertilization Program

What are the chances of success?

As of September 1987, twenty six healthy babies have been born through IVF at Alta Bates Hospital. Although IVF offers a renewed sense of hope to many infertile couples, it is important to have realistic expectations. With the latest techniques, pregnancy can be expected in one out of four treatment cycles. This 25% success rate per attempt is similar to the conception rate of normally fertile couples in a single month. If pregnancy does not ensue, treatment can be repeated with equal chance of conception in subsequent cycles.

What should I expect?

IVF is a complex process consisting of several steps. First, fertility drugs are given to stimulate the ripening of several eggs. Daily blood tests and ultrasound examinations allow precise timing of egg retrieval. Egg retrieval is done either by laparoscopy, a minor surgical procedure performed under general or spinal anesthesia, or non-surgically with the use of ultrasound. With either technique the woman goes home the same day. The sperm is then added to the eggs in the laboratory where the fertilized eggs develop for 2–3 days. Finally, the early embryos (fertilized dividing eggs) are placed in the womb by a simple non-surgical procedure similar to a pelvic examination. If a large number of embryos develop, the rest can be frozen and stored for replacement at a later time. Two weeks after embryo transfer, a blood test is done to determine if pregnancy has been established. For prenatal care, patients return to their obstetricians.

What are the risks of IVF?

The procedure is safe for both the would-be mother and her child. Occasionally, ovarian cysts may form in response to the fertility drugs. Laparoscopy and anesthesia carry the same low risks as in other cases. Apart from the increased chance of multiple birth, the risks of pregnancy and delivery are unchanged. With several thousand children born after IVF worldwide, there has been no increased risk of birth defects or abnormalities.

What is the cost of IVF?

The technique involves the use of expensive drugs, equipment and laboratory tests. The average total cost of a treatment cycle with laparoscopy is $6,000.00. With ultrasound-guided egg retrieval under local anesthesia the average cost is $4,800. The extent of insurance coverage varies widely. Assistance in submitting charges for reimbursement is available.

How can I know if IVF can help me?

Complete evaluation by an infertility specialist is necessary to decide if IVF is appropriate for you. If another form of therapy offers a greater or equal chance of success, it will be offered to you. Our infertility specialist, Dr. Ryszard J. Chetkowski, provides the full range of treatments for infertility such as microsurgery, laser laparoscopy, ovulation induction, hormonal supplementation, artificial insemination and sperm washing.

The team approach

IVF is a complex process which requires a well-coordinated team to attain the best results. For that reason the reproductive endocrinologist and biologist at Alta Bates were both recruited from a single highly successful IVF program. The Medical Director, Dr. R. J. Chetkowski, trained in obstetrics and gynecology at Yale and in reproductive endocrinology at UCLA. In addition to extensive clinical experience, he has published widely on different aspects of infertility and reproductive endocrinology. He is a board-certified obstetrician and gynecologist. At Alta Bates Hospital, Dr. Chetkowski performs all the examinations, ultrasound scans, egg retrievals and embryo transfers assuring maximal continuity of patient care. Working with Dr. Chetkowski is the IVF biologist, Thomas E. Nass, Ph.D. Dr. Nass was also at UCLA where he acquired extensive experience in all laboratory aspects of the IVF process.

On the strength of these credentials and treatment results, the Alta Bates IVF team was the first non-university program in California to be accredited by the American Fertility Society, the national organization of infertility specialists.

Lisa Kruse, R.N. and Lynn Polon, R.N., are our nurse coordinators. They provide individualized care and attention to each couple, answering questions, organizing patient education and assisting with procedures. Counseling and psychological support are an integral part of the treatment program, helping patients cope with the inevitable stress associated with IVF. We are sensitive to the many difficult decisions which are faced by couples undergoing infertility evaluation and treatment. Therefore, patient education is one of our highest priorities. We welcome your questions about our program, because we are committed to providing the best of medical care to a fully informed group of patients. We think of each couple as members of our team working towards a common goal—your successful pregnancy.

For more information about the In Vitro Fertilization Program at Alta Bates Hospital, please call our office at (415) 540-1416 or write to:

R. J. Chetkowski, M.D.
Director of In Vitro Fertilization
Alta Bates Hospital
3001 Colby Street
Berkeley, California 94705

IVF/GIFT SURVEY

CLINIC NAME: CENTRAL CALIFORNIA IVF PROGRAM
ADDRESS: 6215 N. FRESNO SUITE 108
FRESNO CA 93710

CONTACT PERSON: CARLOS SUELDO MD
PHONE NUMBER: (209) 439-[illegible] 1915 or 1914

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? XII|88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    (a) Private X
    (b) Community hospital based X
    (c) University based ______
    (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
    (a) Physicians 2
    (b) Laboratory Scientists (PhDs) 3
    (c) Nurses 1
    (d) Embryo Lab Technicians/Technologists 2
    (e) Other Lab Technicians/Technologists 1
    (f) Radiology (Ultrasound) Technicians —
    (g) Psychologists/Counselors —
    (h) Secretaries 1 1/2
    (i) Other (specify) [illegible]TIONIST

7. How many years has your infertility clinic been in operation? 3

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1985 GIFT 1986

9. How many different patients were stimulated?
1987 IVF 56 1988 IVF 90
GIFT 18 GIFT 36

10. How many stimulation cycles were performed?
1987 IVF 60 1988 IVF 106
GIFT 18 GIFT 40

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 54 1988 86

How many embryo transfer cycles were performed?
1987 39 1988 71

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 9 1988 28

13. What were the number and percentage of patients on IRB approved research protocols?
1987 —0— % 1988 —0— %

14. What were the number and percentage of patients treated for:

Unanswered
See attached letter

(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) Other (explain): ____________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:

(a) <31:
1987 IVF 17 30% 1988 IVF 32 35%
GIFT 0 0% GIFT 7 25%

(b) 31-35:
1987 IVF 29 54% 1988 IVF 40 49%
GIFT 5 55% GIFT 8 28.5%

(c) 36-40:
1987 IVF 7 12.5% 1988 IVF 12 13.5%
GIFT 4 45% GIFT 12 42.5%

(d) 41-45:
1987 IVF 1 2% 1988 IVF 2 2.5%
GIFT 0 0% GIFT 1 4%

(e) >45:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 0 0%

16. How many clinical pregnancies were produced?
1987 IVF 7 1988 IVF 14
GIFT 2 GIFT 11

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 6 1988 IVF ~~3~~ 5
GIFT 3 GIFT 2

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ~~[illegible]~~ 0 1988 IVF 10 ~~[illegible]~~ ~~([illegible] cont. past 16 weeks)~~
GIFT ~~[illegible]~~ 0 GIFT ~~10~~ 8 (continuing past 16 weeks) 10 (8 cont. past 16 weeks)

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF __ __% __________
GIFT __ __% __________
1988 IVF __ __% __________
GIFT __ __% __________

See attached letter

21. What are the qualifications of the director of the embryo laboratory? DVM

22. Who supervises the laboratory director? TEAM INTERACTION

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Applying FOR MEMBERSHIP

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ______
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ______
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

See attached letter

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

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SCHOOL OF MEDICINE
FRESNO-CENTRAL SAN JOAQUIN VALLEY
MEDICAL EDUCATION PROGRAM

Please address reply to:
DEPARTMENT OF OBSTETRICS/GYNECOLOGY
Valley Medical Center
445 South Cedar Avenue
Fresno, California 93702
Telephone: 209-453-5720

February 21, 1989

Mr. Mark Balkin
B363-Rayburn House Office Bldg.
Washington, D.C. 20515

Dear Mr. Balkin:

Enclosed you will find the data that has been requested from our In Vitro Fertilization Program. I apologize for the delay but I was out of the country for personal reasons for over a month, therefore, I delayed putting together the data requested. Perhaps this letter will more clearly define the operation of our program.

I trained in In Vitro Fertilization uder Richard Marrs at the University of Southern California during 1982 and 1983. Our program was put together here in Fresno in 1985 and we obtained one pregnancy that unfortunately ended in miscarriage. In 1986 we obtained our first in vitro fertilization pregnancy that was born November of '86. Since then it has been a progressive increase in the number of patients served as well as in the success rates obtained in our clinic.

I will describe the full experience in 1988. Question #17 is unclear, I am not sure if you want the live infants born from those patients served in 1988 or in the program in general. Anyway, during 1988 we did 106 stimulations for IVF and 86 of those got to egg recovery. Due to various factors (severe male factor problems mainly) only 71 patients had embryo transfers. Of the 71 transfers we obtained 14 clinical pregnancies, 8 singletons and 6 multiples (of the multiple pregnancies 5 are twins and 1 set of triplets). Only one of the singletons aborted, all the rest are already delivered or ongoing pregnancies (at least past 12 weeks).Also during 1988 we performed 28 GIFTS procedures, we obtained 11 clinical pregnancies, 7 singletons and 4 multiples (all four were twins). One of the singleton pregnancies miscarriaged but the other ten pregnancies are already delivered or in progress again past at least 12 weeks.

All patients undergoing GIFT were done under laparoscopic technique and all the IVF patients had egg aspirations under ultrasound guidance transvaginal.

Mr. Mark Balkin

In 1987, 39 patients had embryo transfer. Seven had clinical pregnancies (one tubal pregnancy). All six IUPs are already delivered, five singletons and one set of twins. Of the nine GIFTS, two singletons were delivered. Also, the data on different indications (#14) for GIFT and IVF in 1987-88 is not ready yet. It will be forwarded to you as soon as possible. These numbers will give you an accurate idea of the operation of our clinic, but if more information is needed please do not hesitate to contact me.

Very sincerely,

Carlos E. Sueldo, M.D.
Associate Clinical Professor, UCSF
Director of Infertility and
In Vitro Fertilization

CES/jan

IVF/GIFT SURVEY

CLINIC NAME: Infertility, Gynecology, and Obstetrics Medical Group of San Diego, Inc.
ADDRESS: 9339 Genesee Avenue, Suite 220
San Diego
California 92121

CONTACT PERSON: Susan Bailey Abbott
PHONE NUMBER: (619) 455-7520

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/88

2. Does your clinic perform IVF/GIFT treatments? Yes
   (If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
   - (a) Physicians 1
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2 RN's, 3 LVN's, 3 MA's, 1 Surgical Assistant
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 3
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 0
   - (i) Other (specify) Administrator 1 Bookkeeper 1
     Receptionists 6 Insurance/billing 4

7. How many years has your infertility clinic been in operation? 10 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 1983 GIFT 1987

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF 74
GIFT 1 GIFT 3

10. How many stimulation cycles were performed?
1987 IVF 147 1988 IVF 113
GIFT 1 GIFT 4

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 101 1988 87

How many embryo transfer cycles were performed?
1987 77 1988 55

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 4

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF 61 54%
GIFT ___ ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 19 17%
GIFT ___ ___% GIFT 0 ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 4 4%
GIFT ___ ___% GIFT 1 25%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF 15 13%
GIFT ___ ___% GIFT 1 25%
(e) Other (explain): anovulation, antisperm Ab, cervical factor
1987 IVF ___ ___% 1988 IVF 14 12%
GIFT ___ ___% GIFT 2 50%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF 15 13%
GIFT ___ ___% GIFT 0 ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF 32 28%
GIFT ___ ___% GIFT 2 50%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF 48 42%
GIFT ___ ___% GIFT 2 50%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF 18 16%
GIFT ___ ___% GIFT 0 ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF 0 ___%
GIFT ___ ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF 11 1988 IVF 9
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 6 1988 IVF 1
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 4
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 2 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 6 100% 5 single, 1 twin
GIFT 0 ___%

1988 IVF 1 100% single
GIFT 0 ___%

21. What are the qualifications of the director of the embryo laboratory? Ph.D. Microbiology/Immunology; 6 years IVF/ET experience, AFS course on Embryo Cryopreservation July 1987

22. Who supervises the laboratory director? Physician

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
CAP Survey

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Application Pending

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

To date, our clinic has had 16 babies born to 15 mothers (one set of twins). There are four ongoing pregnancies. As of June 1988 we switched from a hospital-based program with egg retrieval done by laparoscopy to an office-based IVF/surgiservice center. Egg retrievals are done by ultrasound-guided aspiration with laparoscopy available. The entire IVF/GIFT treatment facility is on site including physicians offices, ultrasound, clinical laboratory, egg recovery/operating room, and embryo culture laboratory. Since establishing our office-based IVF/GIFT program our clinical pregnancy rates for patients under the age of 40 years is 30% per embryo transfer and 17% per stimulation cycle started.

FERTILITY INSTITUTE
igo
INFERTILITY, GYNECOLOGY, & OBSTETRICS
MEDICAL GROUP OF SAN DIEGO, INC.
JOSEPH F. KENNEDY, M.D.
BENITO VILLANUEVA, M.D.
PHILIP E. YOUNG, M.D.
STEPHEN A. HEBERT, M.D.
JEFFREY C. ROLLSTIN, M.D.
SUSAN B. ABBOTT, ESQ
Administrator
SHEILA J. DIMARZO, PH.D.
Laboratory Director

The Fertility Institute (IGO)

Office-based IVF/ET and GIFT Program 1988

All Patients

			%A	%B	%C	%D
A.	# Cycles Started	59	-	-	-	-
B.	# Retrieval Attempts	49	83%	-	-	-
C.	# Embryo Transfers	31	53%	63%	-	-
D.	# Clinical Pregnancies	7	12%	14%	23%	-
E.	# Ongoing Pregnancies	5	8%	10%	16%	71%

17% of all cycles started were cancelled prior to retrieval.
12% of all cycles started resulted in a clinical pregnancy.
23% of all embryo transfers resulted in a clinical pregnancy.

Patients Under 40 Years of Age

			%A	%B	%C	%D
A.	# Cycles Started	42	-	-	-	-
B.	# Retrieval Attempts	37	88%	-	-	-
C.	# Embryo Transfers	23	55%	62%	-	-
D.	# Clinical Pregnancies	7	17%	19%	30%	-
E.	# Ongoing Pregnancies	5	12%	14%	22%	71%

12% of all cycles started were cancelled prior to retrieval.
17% of all cycles started resulted in a clinical pregnancy.
30% of all embryo transfers resulted in a clinical pregnancy.

Patients 40 Years of Age or Older

			%A	%B	%C	%D
A.	# Cycles Started	17	-	-	-	-
B.	# Retrieval Attempts	12	71%	-	-	-
C.	# Embryo Transfers	8	47%	67%	-	-
D.	# Clinical Pregnancies	0	0%	0%	0%	-
E.	# Ongoing Pregnancies	0	0%	0%	0%	0%

29% of all cycles started were cancelled prior to retrieval.
0% of all cycles started resulted in a clinical pregnancy.
0% of all embryo transfers resulted in a clinical pregnancy.

9339 Genesee Avenue
Suite 220
San Diego, CA 92121
(619) 455-7520

IVF/GIFT SURVEY

CLINIC NAME: University of California Irvine/Memorial Women's IVF/GIFT Program
ADDRESS: 2880 Atlantic Avenue
Suite 220
Long Beach, CA 90806

CONTACT PERSON: Bill Yee, M.D.
PHONE NUMBER: (213) 595-2229

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Oct. '88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    (a) Private ____
    (b) Community hospital based ____
    (c) University based X
    (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
    (a) Physicians ____
    (b) Laboratory Scientists (PhDs) ____
    (c) Nurses 3
    (d) Embryo Lab Technicians/Technologists 3
    (e) Other Lab Technicians/Technologists ____
    (f) Radiology (Ultrasound) Technicians ____
    (g) Psychologists/Counselors ____
    (h) Secretaries 2
    (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? 2½

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF July '86 GIFT July '86

9. How many different patients were stimulated?
1987 IVF 197 1988 IVF 183
GIFT 138 GIFT 193

10. How many stimulation cycles were performed?
1987 IVF 239 1988 IVF 263
GIFT 189 GIFT 248

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 163 1988 188

How many embryo transfer cycles were performed?
1987 152 1988 178

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 151 1988 156

13. What were the number and percentage of patients on IRB approved research protocols?
1987 335 100% 1988 376 100%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 211 88% 1988 IVF 204 78%
GIFT 15 8% GIFT 31 13%
(b) Endometriosis:
1987 IVF 8 3% 1988 IVF 16 6%
GIFT 64 34% GIFT 81 33%
(c) Male infertility:
1987 IVF 10 4% 1988 IVF 17 7%
GIFT 48 25% GIFT 28 11%
(d) Unexplained infertility:
1987 IVF 2 1% 1988 IVF 4 2%
GIFT 30 16% GIFT 31 13%
(e) Other (explain): Adhesions, sperm antibodies
1987 IVF 6 3% 1988 IVF 22 8%
GIFT 32 17% GIFT 77 31%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 36 15% 1988 IVF 28 11%
GIFT 27 14% GIFT 31 13%
(b) 31-35:
1987 IVF 107 45% 1988 IVF 106 40%
GIFT 87 46% GIFT 97 39%
(c) 36-40:
1987 IVF 82 34% 1988 IVF 109 41%
GIFT 68 36% GIFT 86 35%

(d) 41-45:
1987 IVF 14 6% 1988 IVF 20 8%
GIFT 7 4% GIFT 34 14%
(e) >45:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 0 0%

16. How many clinical pregnancies were produced?
1987 IVF 36 1988 IVF 39
GIFT 41 GIFT 47

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 27 1988 IVF 4
GIFT 29 GIFT 10

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ____ 1988 IVF 25
GIFT ____ GIFT 30

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 1 GIFT 2

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 3% (Twins)
GIFT 8 20% (Twins) 1 2% (Triplets)

1988 IVF 5 13% (Twins) 2 5% (Triplets)
GIFT 6 17% (Twins) 1 2% (Triplets)

21. What are the qualifications of the director of the embryo laboratory? Clinical IVF - 5 years Sperm - Egg interactions since 1979. Renowned for work on sperm acrosome reaction

22. Who supervises the laboratory director? IVF Director

23. Does the clinic participate in an external laboratory proficiency testing program? No.
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Applied for

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians One
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists One
    (d) Nurses ______
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The UCI/Memorial Women's IVF/GIFT Program helped to pioneer human embryo freezing in the United States. Five pregnancies have been established - three delivered, one ongoing and one miscarried from 54 attempts.

Our program does not discriminate against women over the age of 40. The chances of achieving a viable pregnancy is substantially lower in this age group. These patients are fully informed prior to IVF or GIFT. We recommend against IVF or GIFT for women over age 42, but will not exclude them from treatment solely based on age.

IVF/GIFT SURVEY

CLINIC NAME: Hospital of Good Samaritan, Institute for Reproductive Medicine
ADDRESS: 1245 Wilshire Bl. #905
Los Angeles, CA 90017

CONTACT PERSON: Richard P. Marrs, M.D.
PHONE NUMBER: (213) 482-4552

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/88.

2. Does your clinic perform IVF/GIFT treatments? Yes.
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians 2
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 4
   - (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 7

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1981 GIFT 1986

9. How many different patientc were stimulated?
1987 IVF Not Known 1988 IVF 154
GIFT Not Known GIFT 150

10. How many stimulation cycles were performed?
1987 IVF 402 1988 IVF 208
GIFT 417 GIFT 200

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 304 1988 149

How many embryo transfer cycles were performed?
1987 267 1988 136

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 219 1988 129

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 100% 1988 ___ 100 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 279 92 % 1988 IVF 143 96 %
GIFT 10 5 % GIFT 4 3 %
(b) Endometriosis:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 53 24 % GIFT 21 17 %
(c) Male infertility:
1987 IVF 25 8 % 1988 IVF 6 4 %
GIFT 68 31 % GIFT 52 40 %
(d) Unexplained infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 88 40 % GIFT 52 40 %
(e) Other (explain): N/A
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 39 13 % 1988 IVF 16 11 %
GIFT 31 14 % GIFT 13 10 %
(b) 31-35:
1987 IVF 119 39 % 1988 IVF 55 37 %
GIFT 75 34 % GIFT 39 30 %
(c) 36-40:
1987 IVF 112 37 % 1988 IVF 60 40 %
GIFT 75 34 % GIFT 51 40 %

(d) 41-45:
1987 IVF 34 11 % 1988 IVF 18 12 %
GIFT 38 17 % GIFT 23 18 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 1 1 % GIFT 3 2 %

16. How many clinical pregnancies were produced?
1987 IVF 44 1988 IVF 25
GIFT 60 GIFT 36

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 31 1988 IVF -
GIFT 42 GIFT -

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF Delivered 1988 IVF 19
GIFT Delivered GIFT 26

19. How many ectopic pregnancies resulted?
1987 IVF 2 1988 IVF 1
GIFT 3 GIFT 2

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 6 19 % Twins (2), Triplets (4)
GIFT 11 26 % Twins (8), Triplets (3)

1988 IVF 3 16 % Twins (3)
GIFT 6 23 % Twins (6)

21. What are the qualifications of the director of the embryo laboratory? Ph.D., 15 years of experience in animal and human gamete and embryo work.

22. Who supervises the laboratory director? Institute Director
Richard P. Marrs, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 12
    (b) Laboratory scientists (PhDs) 4
    (c) Embryo laboratory technicians/technologists numerous
    (d) Nurses numerous
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Our clinic is the second clinic to be established in the United States opening in September, 1981 and delivering our first infant from IVF-ET in June 1982. All patients that are treated in our center are referred by a physician and accepted if all diagnostic and infertility treatment modalities have been completed. Approximately 20% of patients have had one or more failed treatment cycles at centers prior to treatment at our center, moreover all patients treated in our center are placed onto IRB approved research protocols.

The statistics for 1988 are for the months of May through December as our program underwent major personel and physical plant changes in the beginning of 1988. In May 1988 the Institute for Reproductive Medicine was established and these are the results of the first eight months. A new procedure started late in the year wes Zygote intrafallopian transfer (ZIFT) of which we have performed nine (9) procedures with five (5) clinical ongoing pregnancies. Finally we recently have delivered the eleventh infant from a frozen embryo transfer procedure.

RICHARD P. MARRS M.D.
REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY

1245 WILSHIRE BOULEVARD, SUITE 905
LOS ANGELES, CALIFORNIA 90017
(213) 482-4552

January 6, 1988

Congressman Ron Wyden
3D District, Oregon
500 NE Multnomah, Suite 250
Portland, OR 97232

Dear Congressman Wyden:

I am sorry for the delay in getting this questionaire completed but we performed our last egg recovery on December 21, 1988 thus outcomes are not available for about 20 cycles. However, I have submitted all cycle outcomes done and considered no pregnancies in the last 15-20 cycles. Obliviously we will have some (I hope), but it won't effect the data that much.

I hope that this information will be utilized to the best advantage for the patient. I am somewhat disappointed that because of my strong stand concerning these issues, I seem to have been excluded by the AFS representation. I hope that when it is time to analyzed and publish this data you will be able to find a way for me to be involved.

Please give my regards to D'Ann and I look forward to working with you and your staff in making 1989 a very active and productive year.

Sincerely,

Richard P. Marrs

Richard P. Marrs, M.D.
Director, Institute for Reproductive Medicine

RPM/11

Enc.

IVF/GIFT SURVEY

CLINIC NAME: UCLA Medical Center
ADDRESS: Fertility Center

CONTACT PERSON: Dr. J.C. Gambone
PHONE NUMBER: (213) 825-7755

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? December 1988

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    - (a) Private ______
    - (b) Community hospital based ______
    - (c) University based X
    - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3 Board Certified

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
    - (a) Physicians 3
    - (b) Laboratory Scientists (PhDs) 1
    - (c) Nurses 3
    - (d) Embryo Lab Technicians/Technologists 2
    - (e) Other Lab Technicians/Technologists 1
    - (f) Radiology (Ultrasound) Technicians 0
    - (g) Psychologists/Counselors 0
    - (h) Secretaries 2
    - (i) Other (specify) 1 Receptionist

7. How many years has your infertility clinic been in operation? 1980 as a "clinic".Infertility care has been available by certified specialists since 1950's.

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 Sep. GIFT 1984

9. How many different patients were stimulated?
1987 IVF 134 1988 IVF 72
GIFT 2 GIFT 0

10. How many stimulation cycles were performed?
1987 IVF 152 1988 IVF 105
GIFT 2 GIFT 0

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 122 1988 98

How many embryo transfer cycles were performed?
1987 110 1988 90

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 2 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 46 34 % 1988 IVF 30 42 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 42 31 % 1988 IVF 14 19 %
GIFT 0 0 % GIFT 0 0 %
(c) Male infertility:
1987 IVF 27 20 % 1988 IVF 19 26 %
GIFT 0 0 % GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 19 14 % 1988 IVF 9 12 %
GIFT 2 100 % GIFT 0 0 %
(e) Other (explain): ____________
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 10 7 % 1988 IVF 7 10 %
GIFT 0 0 % GIFT 0 0 %
(b) 31-35:
1987 IVF 35 26 % 1988 IVF 23 32 %
GIFT 2 100 % GIFT 0 0 %
(c) 36-40:
1987 IVF 83 62 % 1988 IVF ~~22~~ 35 ~~44~~ % 49%
GIFT 0 0 % GIFT 0 0 %

(d) 41-45:
1987 IVF 6 5 % 1988 IVF 7 10 %
GIFT 0 0 % GIFT 0 0 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 26 1988 IVF 18
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 22 1988 IVF 8
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 8
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 1
GIFT 1 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 5 23 % 2 twin, 2 triplets, 1 goad
GIFT 0 0 %

1988 IVF 2 25 % 1 twin, 1 triplet
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? Board certified reproductive endocrine and Ph.D.

22. Who supervises the laboratory director? Director of program

23. Does the clinic participate in an external laboratory proficiency testing program? no
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? yes

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
- **(a) Physicians** 9
- **(b) Laboratory scientists (PhDs)** 2
- **(c) Embryo laboratory technicians/technologists** ____
- **(d) Nurses** 3
- **(e) Other (explain)** ____

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

UCLA has a fertility center within the Department of Obstetrics and Gynecology. It is located in the UCLA Medical Center in Westwood. In addition to IVF-ET ovulation induction and donor insemination are available.

Since 1987 all IVF-ET procedures are done outside the operating room using vaginal ultrasound retrieval.

GIFT will be offered as soon as techniques are developed to perform this procedure without a general anesthetic and operative procedure.

All fertility treatment is given or supervised by board certified (in Reproductive Endocrinology) members of the faculty of UCLA School of Medicine. The number of cycles that can be performed in one year can vary depending on the number of qualified faculty members who are available to perform IVF-ET in that year.

IVF/GIFT SURVEY

CLINIC NAME: University of Southern California School of Medicine
ADDRESS: California Reproductive Health Institute
1338 South Hope Street
Los Angeles, California 90015

CONTACT PERSON: Richard J. Paulson, M.D. , Ann Moegle, R.N.
PHONE NUMBER: (213) 742-5970

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based x
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 4

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 0
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 2
   - (i) Other (specify) 0

7. How many years has your infertility clinic been in operation? 2 1/2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF September 1986 GIFT September 1986

9. How many different patients were stimulated?
1987 IVF 77 1988 IVF 134
GIFT 20 GIFT 4

10. How many stimulation cycles were performed?
1987 IVF 113 1988 IVF 161
GIFT 22 GIFT 3

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 84 1988 146

How many embryo transfer cycles were performed?
1987 69 1988 133

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 22 1988 2

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 10 6 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 41 53 % 1988 IVF 73 54 %
GIFT 1 5 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 16 21 % 1988 IVF 36 27 %
GIFT 3 15 % GIFT 1 50 %
(c) Male infertility:
1987 IVF 6 8 % 1988 IVF 6 4 %
GIFT 2 10 % GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 10 12 % 1988 IVF 16 12 %
GIFT 19 95 % GIFT 1 50 %
(e) Other (explain): Ovarian Failure
1987 IVF 1 1 % 1988 IVF 12 9 %
GIFT 0 0 % GIFT 0 0 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 17 22 % 1988 IVF 30 22 %
GIFT 4 20 % GIFT 0 0 %
(b) 31-35:
1987 IVF 35 45 % 1988 IVF 62 46 %
GIFT 10 50 % GIFT 2 100 %
(c) 36-40:
1987 IVF 19 25 % 1988 IVF 32 24 %
GIFT 6 30 % GIFT 0 0 %

(d) 41-45:
1987 IVF 7 9 % 1988 IVF 10 7 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 1 1 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 17 1988 IVF 35
GIFT 9 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 10 1988 IVF 10
GIFT 3 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 15
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 1 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 3 30 % 3 twins
GIFT 0 0 %

1988 IVF 3 30 % 3 twins
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? Reproductive Endocrinologist

22. Who supervises the laboratory director? Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 7
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses 0.
    (e) Other (explain) 0

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

See attached

University of Southern California School of Medicine
California Reproductive Health Institute

Additional data

A) Non-Anonymous donor oocyte program - 1988 results
- -performed by standard IVF methods
- -all recipients with premature ovarian failure
- -all donors ≤ 35 yrs old, previously pregnant

6 patients (recipients)
9 cycles
5 pregnancies, 3 delivered, 2 ongoing

4 twins
1 singleton

B) Best group success rate - 1988 results
(note that this is a sub-group or the general 1988 results)

patients ≤ 35 yrs old, previously pregnant

37 embryo transfer
13 pregnancies (35%)
9 ongoing pregnancies (24%)

C) Over 40 success rate - 1987 and 1988

24 cycles
20 embryo transfers
4 pregnancies (20%)
2 live births (10%)

Oldest patient with live birth= 43 yrs old

IVF/GIFT SURVEY

CLINIC NAME: SOUTHERN CALIFORNIA FERTILITY INSTITUTE

ADDRESS:
California Institute for IVF – RTP Program
#415, 12301 Wilshire Boulevard
Los Angeles, California 90025

CONTACT PERSON: William G. Karow, M.D.

PHONE NUMBER: (213) 820-3723

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    (a) Private X
    (b) Community hospital based ________
    (c) University based ________
    (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? one

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? one

6. How many other professionals participate in your clinic?
    (a) Physicians one
    (b) Laboratory Scientists (PhDs) one
    (c) Nurses two
    (d) Embryo Lab Technicians/Technologists one
    (e) Other Lab Technicians/Technologists two
    (f) Radiology (Ultrasound) Technicians two
    (g) Psychologists/Counselors one
    (h) Secretaries two
    (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 13 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1985 , GIFT 1987

9. How many different patients were stimulated?
1987 IVF ___17 1988 IVF ___12
GIFT ___10 GIFT ___30

10. How many stimulation cycles were performed?
1987 IVF ___20 1988 IVF ___17
GIFT ___10 GIFT ___33

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ___17 1988 ___12

How many embryo transfer cycles were performed?
1987 ___15 1988 ___12

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ___10 1988 ___30

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 17 ___% 1988 IVF 12 ___%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ___________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 5 29% 1988 IVF 3 25%
GIFT 3 30% GIFT 8 27%
(b) 31-35:
1987 IVF 3 18% 1988 IVF 4 33%
GIFT 6 60% GIFT 7 23%
(c) 36-40:
1987 IVF 6 35% 1988 IVF 4 33%
GIFT 1 10% GIFT 11 37%

(d) 41-45:
1987 IVF 3 18% 1988 IVF 1 6%
GIFT 0 % GIFT 5 11%
(e) >45:
1987 IVF 0 % 1988 IVF 0 %
GIFT 0 % GIFT 0 %

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 2
GIFT 1 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF
GIFT 1 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 %
GIFT 0 %

1988 IVF 0 %
GIFT 0 %

21. What are the qualifications of the director of the embryo laboratory? B.Sc. - Hons. - Ph.D. (Australia)

22. Who supervises the laboratory director? Clinic Physician

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 0
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 1
    (d) Nurses 0
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The clinic's IVF/GIFT program was re-established in June, 1987 and the majority of work has occurred in 1988. Many of the initial patients were previous IVF patients who had failed to conceive.

Embryo freezing is performed in this clinic and successful pregnancies have resulted. Even with a small sample, success rates are well within the highest acceptable levels expected for IVF and GIFT.

IVF/GIFT SURVEY

CLINIC NAME: Fertility and Reproductive Health Institute of Northern California
ADDRESS: 2516 Samaritan Drive, Suite A
San Jose, California 95124

CONTACT PERSON: G. David Adamson, M.D.
PHONE NUMBER: (408) 358-2500

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 10-31-88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based X
   - (c) University based ____
   - (d) Other (explain) X

Limited Partnership: Drs. Adamson and Sgarlata. General Partners: Good Samaritan Hospital and Physicians Limited Partners.

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 0

6. How many other professionals participate in your clinic?
   - (a) Physicians 2 (Urologists)
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 3
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) 1 (Medical Assistant)

7. How many years has your infertility clinic been in operation? 3 months

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 9-8-88 GIFT 9-22-88

9. How many different patients were stimulated?
1987 IVF 0 1988 IVF 13
GIFT 0 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 0 1988 IVF 13
GIFT 0 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 0 1988 13

How many embryo transfer cycles were performed?
1987 0 1988 10

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 0 0 % 1988 IVF 7 54 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 0 0 % 1988 IVF 1 8 %
GIFT 0 0 % GIFT 1 100 %
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 5 38 %
GIFT 0 0 % GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %
(e) Other (explain): Note: Five patients had multiple factors. Only most important reported.
1987 IVF 0 0 % 1988 IVF ____ ____ %
GIFT 0 0 % GIFT 0 0 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 0 % 1988 IVF 1 8 %
GIFT 0 0 % GIFT 0 0 %
(b) 31-35:
1987 IVF 0 0 % 1988 IVF 6 46 %
GIFT 0 0 % GIFT 0 0 %
(c) 36-40:
1987 IVF 0 0 % 1988 IVF 6 46 %
GIFT 0 0 % GIFT 1 100 %

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 6
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 5 (all with fetal heart tones on ultrasound)
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 % __________
GIFT 0 0 % __________

1988 IVF 0 0 % __________
GIFT 0 0 % __________

21. What are the qualifications of the director of the embryo laboratory? Ph.D. Neurosciences, University of Wisconsin. Started two previous IVF programs with Dr. David Meldrum & Dr. Richard Chetkowski.

22. Who supervises the laboratory director? Dr. Thomas Nass

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes, except we are not performing our cycles under an experimental protocol.

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** We have applied and expect Provisional Membership based on Dr. Nass's membership.

27. **Does the clinic train individuals in IVF or GIFT?** Yes **If the answer is yes, how many individuals in the following specialties have been trained?**
    (a) **Physicians** 0
    (b) **Laboratory scientists (PhDs)** 0
    (c) **Embryo laboratory technicians/technologists** 1
    (d) **Nurses** 1
    (e) **Other (explain)** ________

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

Our patient population has been derived largely from the referral practices of the Institute's reproductive endocrinologists, with many of our patients having multiple infertility factors. Our upper age limit is 43. After extensive consultation we treat patients based on their individual needs. All patients have pre- and post-cycle visits with our psychotherapist to enhance their ability to manage the emotional aspects of an IVF cycle. We use Lupron and Pergonal for all patients, and transvaginal retrieval in an operating room under IV sedation. While we are a new IVF program, all of our staff have had experience in IVF and/or infertility programs. We feel our early success reflects this experience and our commitment to each patient. As of December 8, 1988, we have 8 patients with positive pregnancy tests in 18 IVF treatment cycles and 1 of 2 GIFT cycles. We also have 43 frozen embryos from 10 patients.

Fertility and Reproductive Health Institute of Northern California

G. David Adamson, M.D. FRCS(C)
FACOG, FACS, Director

Carmelo S. Sgarlata, M.D.
FACOG, Co-Director

Advisory Board
Barry D. Brummer, M.D., FACOG
Ali Hoda, M.D., FACOG
John Kersten Kraft, M.D.
Gerald Trobough, M.D., FACOG
Gul Zikria, M.D., FACOG

2516 SAMARITAN DRIVE, SUITE A
SAN JOSE, CA 95124
408/358-2555

December 29, 1988

Assemblyman Ron Wyden
Congress of the United States
Suite 1406
Longworth House Office Building
Washington D.C. 20515

RE: IVF/GIFT Survey

Dear Assemblyman Wyden:

I am writing on behalf of the Fertility and Reproductive Health Institute of Northern California. We have completed, and sent by certified mail to you, a response to your survey and you should have received this prior to your 12-15-88 deadline.

I am writing this letter to clarify a response to question number 22 in which I indicated that the person who supervised the Laboratory Director was Dr. Thomas Nass. In fact, Dr. Thomas Nass is the Laboratory Director and he is supervised by Drs. David Adamson and Carmelo S. Sgarlata. I have called your office on 12-22-88 to give this corrected information and simply am sending this letter to confirm the error in the first response.

Thank you very much for your attention to this. Please contact me if you have any further questions.

Yours truly,

G. David Adamson, md mam

G. DAVID ADAMSON, M.D.

GDA:mam

IVF/GIFT SURVEY

CLINIC NAME: NOVA FERTILITY CENTER
ADDRESS: 101 S. san Mateo Drive #201
San Mateo, Calif. 94401

CONTACT PERSON: Francis F. Polansky, M.D.
PHONE NUMBER: (415)340-0500

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the never clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 2-21-89

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   - (a) Physicians 1
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 0
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 0
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 2
   - (i) Other (specify) MEDICAL ASSISTANTS (2)

7. How many years has your infertility clinic been in operation? 2nd year

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 10-87 GIFT 10-87

9. How many different patients were stimulated?
1987 IVF 5 1988 IVF 59 1989 IVF 19
GIFT 4 GIFT 12 1989 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 5 1988 IVF 80 1989 IVF 19
GIFT 4 GIFT 19 1989 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 5 1988 54 1989 14

How many embryo transfer cycles were performed?
1987 4 1988 51 1989 14

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 3 1988 9 1989 2

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 4 80 % 1988 IVF 31 38 % 1989 IVF 7 37 %
GIFT 0 0 % GIFT 0 0 % 1989 GIFT 0 0 %
(b) Endometriosis:
1987 IVF 0 0 % 1988 IVF 2 3 % 1989 IVF 1 5 %
GIFT 1 25 % GIFT 3 16 % 1989 GIFT 0 0 %
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 16 20 % 1989 IVF 4 21 %
GIFT 0 0 % GIFT 1 5 % 1989 GIFT 1 100 %
(d) Unexplained infertility:
1987 IVF 0 0 % 1988 IVF 25 31 % 1989 IVF 6 32 %
GIFT 3 75 % GIFT 14 74 % 1989 GIFT 0 0 %
(e) Other (explain): ♂+♀factor, 2 POF
1987 IVF 1 20 % 1988 IVF 6 7.5 % 1989 IVF 1 5 %
GIFT 0 0 % GIFT 1 5 % 1989 GIFT 0 0 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 0 % 1988 IVF 4 5 % 1989 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 % 1989 GIFT 0 0 %
(b) 31-35:
1987 IVF 4 80 % 1988 IVF 36 45 % 1989 IVF 7 37 %
GIFT 1 25 % GIFT 3 16 % 1989 GIFT 0 0 %
(c) 36-40:
1987 IVF 1 20 % 1988 IVF 35 44 % 1989 IVF 11 58 %
GIFT 2 50 % GIFT 12 63 % 1989 GIFT 1 100 %

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 5 6 % 1989 IVF 1 5 %
GIFT 1 25 % GIFT 4 21 % 1989 GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 % 1989 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 % 1989 GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 1 1988 IVF 16 1989 IVF 5
GIFT 0 GIFT 3 1989 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 4 1989(JAN/FEB) IVF 3
GIFT 0 GIFT 2 1989(JAN/FEB) GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 1 1988 IVF 9 1989 IVF 5
GIFT 0 GIFT 1 1989 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 2 1989 IVF 0
GIFT 0 GIFT 0 1989 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 % -----
GIFT 0 0 % -----

1988 IVF 2 50 % 2 Sets of twins
GIFT 1 50 % 1 Set of twins
1989 IVF 0 0 % 3 Singletons GIFT 0 0 % 1 Single

21. What are the qualifications of the director of the embryo laboratory? 6.5 years of IVF laboratory experience.
Univ. of Texas--Houston, Stanford Univer., Nova Fertility Center.

22. Who supervises the laboratory director? Clinic Director

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
----

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

We are the only office-based IVF/GIFT program in California and one of very few nation-wide. Our treatments include: Embryo freezing and egg donation program. We use local anesthesia for GIFT procedures.

5
5
10

IVF/GIFT SURVEY

CLINIC NAME: Century City Hospital
ADDRESS: 2070 1 Century Park East
Los Angeles, CA 90067

CONTACT PERSON: DR. DAVID HILL.
PHONE NUMBER: 213 201-6619

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the never clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 7

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 9

6. How many other professionals participate in your clinic?
   - (a) Physicians ______
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2½
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists ______
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) Andrologist. Dr. Cappy Rothman

7. How many years has your infertility clinic been in operation? 5 (restarted March 1987) (limited 1983—1987)

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 1983 GIFT Jan 1987.

9. How many different patients were stimulated?
1987 IVF 73 1988 IVF 132
GIFT 37 GIFT 123

10. How many stimulation cycles were performed?
1987 IVF 84 1988 IVF 185
GIFT 47 GIFT 145

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 89 1988 152

How many embryo transfer cycles were performed?
1987 10 1988 24

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 47 1988 145

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 56 51% 1988 IVF 159 74%
GIFT 0 0% GIFT 0 0%
(b) Endometriosis:
1987 IVF 7 6% 1988 IVF 2 1%
GIFT 3 5% GIFT 21 13%
(c) Male infertility:
1987 IVF 23 21% 1988 IVF 23 11%
GIFT 16 27% GIFT 63 40%
(d) Unexplained infertility:
1987 IVF 18 16% 1988 IVF 11 5%
GIFT 38 65% GIFT 68 43%
(e) Other (explain): Surrogate
1987 IVF 5 4% 1988 IVF 15 5%
GIFT 1 2% GIFT 7 4%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 14 21% 1988 IVF 57 25%
GIFT 6 12% GIFT 21 14%
(b) 31-35:
1987 IVF 36 43% 1988 IVF 74 40%
GIFT 25 48% GIFT 45 30%
(c) 36-40:
1987 IVF 20 26% 1988 IVF 41 22%
GIFT 12 25% GIFT 60 40%

(d) 41-45:
1987 IVF 10 11 % 1988 IVF 15 10 %
GIFT 6 12 % GIFT 24 16 %

(e) >45:
1987 IVF 2 2 % 1988 IVF 1 13 %
GIFT 1 2 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 11 1988 IVF 32
GIFT 18 GIFT 35

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 2 1988 IVF 11
GIFT — GIFT 16

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF — 1988 IVF 18
GIFT — GIFT 17

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 2
GIFT 2 GIFT —

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 — %
GIFT 0 — %

1988 IVF 1 10 % Twins
GIFT 3 18 % 2 sets twins, 1 set triplets

21. What are the qualifications of the director of the embryo laboratory? PhD, Immunology

22. Who supervises the laboratory director? Hospital Chief Executive Officer

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** yes

27. **Does the clinic train individuals in IVF or GIFT?** yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) **Physicians** 2 winer, Chamonki
    (b) **Laboratory scientists (PhDs)** 0
    (c) **Embryo laboratory technicians/technologists** 2
    (d) **Nurses** 3
    (e) **Other (explain)** 0

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

Our program consists of infertile couples of which approximately 20% have a female partner aged 40 or more. All are private pay, few are covered for IVF or GIFT through insurance. The Program has several (6) physician offices referring patients, who undergo serologic and ultrasound exams at the Program Hospital. Seventy percent of all patients are administered leuprolide acetate as part of their controlled ovarian stimulation protocol. No babies have been born with congenital abnormalities. The Program is currently starting a program for micromanipulation methodology for severe male factor which should be available clinically by 5/89. There is a 2-month waiting list at our Program for IVF or GIFT. There are over 30 oocyte retrievals performed each month, around a third of which are GIFT. There is a support group sponsored by the Program.

CENTURY
CITY
HOSPITAL

2070 CENTURY PARK EAST
LOS ANGELES, CA 90067
(213) 553-6211

February 23, 1989

Mr. Mark Balkin
c/o Ron Wyden Office
1406 Longworth House Office Bldg.
House of Representatives
Washington, D. C. 20515

Dear Mr. Balkin:

The discrepancy in the data on item #11 we reported can be explained as follows:

In 1987 we performed 10 cycles of GIFT/IVF combinations, which were reported as embryo transfers. If one subtracts this number from what we reported, one gets 80 embryo transfers instead of the 90 we originally reported.

For 1988, there were 24 GIFT/IVF cycles. Additionally, there were 6 patients who had "double" embryo transfers, and 5 who had frozen embryo transfers. This equals 36 procedures for which a direct egg retrieval was not accounted for.

I hope this is of help to you in ciphering the Century City Hospital data.

Data not asked for: Retrievals, but no ET due to failed fertilization, no oocytes obtained, etc.

1987	1988
8	13

Sincerely,

David L. Hill

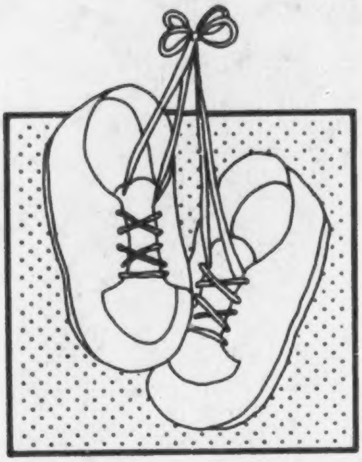
David L. Hill, Ph.D.
Director, IVF Laboratory
Century City Hospital
(213) 201-6604

A National Medical Enterprises Health Care Center

And now our family is complete!

CENTER
FOR
REPRODUCTIVE
MEDICINE

CENTURY CITY HOSPITAL



THE NATURE OF MIRACLES AND HARD SCIENCE

If anything can be both entirely natural and miraculous, then the birth of a baby is it. But what comes so naturally to so many, nature has denied to almost one couple in five.

In 1978, all that began to change in England. A mother's egg and a father's sperm were put into a glass dish ("In Vitro" means "in glass"). In vitro fertilization (IVF) took place, the egg was transferred back into the mother and the pregnancy proceeded naturally to a live birth.

Since then, thousands of healthy babies have been born to couples who had previously been told they could never bear children. Yet the truth still remains that while hard science has brought hope to many, the process can not yet be thought of as simple or certain. The chances now, if not yet probable, are, at least, possible. Those chances improve when three vital elements are combined: 1) a couple with complete dedication, 2) a hospital with truly state-of-the-art facilities, and 3) a medical staff with impeccable credentials, lots of experience, and honest concern.

This is not just talk. The fact that couples must carefully investigate the facilities under their consideration never became more clear than when several leading American experts noted in the prestigious publication *Fertility and Sterility:* ". . . half of the IVF programs that have been established in the country have *no* pregnancies . . ." (Vol. 48, No. 5, November 1987, pg. 737).

When half of the nation's infertility programs have never produced a successful birth . . .
—when many people spend years and great amounts of money on totally inappropriate means of achieving pregnancy—oftentimes without thorough testing of both partners first . . .
—when many continue going to general practitioners about a highly specialized problem . . .
then we can only urge those who earnestly want children, to see a qualified, board-certified specialist at a fully equipped facility with a proven track record . . . a facility such as Century City Hospital.

CENTURY CITY HOSPITAL . . . ADVANCED TECHNOLOGY AND CARING STAFF

Century City Hospital has established a reputation for a high rate of successful IVF births based on two priorities: dedication to employing the latest, proven technical advances in the field combined with a dedicated understanding to the human uniqueness of each individual case. Our rate of successful pregnancies is especially noteworthy because we accept many older and high risk applicants not accepted by other facilities.

In vitro fertilization and embryo transfer is a highly advanced, complex procedure requiring the concerted efforts of many physicians, scientists, and other health professionals. Century City Hospital approaches each case as a team effort. Our IVF team members include your gynecologist, our medical director, and our experts from the fields of reproductive biology, gynecology, nursing, and andrology/urology.

Every successful pregnancy here is a cause for rejoicing for our staff almost as much as for the future parents themselves. Our doctors and nurses spend as much time with each couple as each case requires. There can be no simple textbook approach to procedures as individual and unique as these necessarily are, and our staff is encouraged to spend the needed time with each patient. Set up an appointment to come in or just call to talk about your particular situation over the phone. We think you'll find that we're good listeners.

Among the services our Center for Reproductive Medicine offers, are:

- **In Vitro Fertilization and Embryo Transfer (IVF/ET)**
  Laboratory fertilization of sperm and eggs collected from a couple and transferred to the uterus where pregnancy can be established.

- **Gamete Intra-Fallopian Transfer (G.I.F.T.)**
  Placement of a couple's own sperm and unfertilized eggs within the fallopian tube where fertilization can take place "naturally" inside the woman's body.

* * *

- **IVF Surrogate Pregnancy**
  Using the sperm and eggs of the biological couple, a carefully screened surrogate is implanted with the in vitro fertilized embryo.

- **Cryobank**
  Freezing and storage for future use in repeat IVF procedures or for use as donors to single women wishing to become pregnant.

- **Ultrasound Guided Egg Retrieval**
  Using continuous ultrasound monitoring, eggs are retrieved from each follicle under general or local anesthesia.

- **Andrology**
  Study of the male reproductive system, including expert diagnosis and treatment, male infertility testing, semen analysis, and cryopreservation of the sperm (sperm banking).

- **Vasovasostomy**
  A highly successful outpatient, microscopic, surgical procedure which reverses vasectomy.

- **Tuboplasty**
  For correction and/or reconstruction of obstructed fallopian tubes utilizing modern laser techniques, which are also used in the treatment of endometriosis (displaced uterine fragments).

WHO SHOULD SEE US?

If a couple has been trying to achieve pregnancy for over one year unsuccessfully, it is time for them to consider a facility such as Century City Hospital for an initial consultation. Among the common causes of infertility are:

- **Tubal Disease,** including blocked or absent fallopian tubes
- **Male Factors,** such as low sperm count or poor sperm motility
- **Unexplained infertility,** in which all tests performed to date have resulted in "Normal" or inconclusive findings
- **Immunologic factors,** such as presence of paternal or maternal anti-sperm antibodies
- **Endometriosis,** displaced uterine fragments for which medical and surgical treatment have not yet been successful

In addition to infertile couples, many people interested in surrogate or oocyte (ovum) donor procedures consult with Century City Hospital because of our considerable experience in these fields.

The coordinator of our IVF/ET program will meet with candidates initially to review their history, set up their appointment with the physicians, and ask for certain records.

CENTURY CITY HOSPITAL'S IVF PROCEDURE

Ideally, patients concerned with infertility would contact the hospital early on for a referral to one of the program's IVF specialists. This physician's examination of both partners and an understanding of the history and unique circumstances of each couple are the starting points from which the most effective strategy for conception can be determined.

From this point, a time schedule can be worked out. Century City Hospital's IVF/ET program works to maintain a minimal waiting period, but exceptionally urgent cases will be treated as soon as possible.

Once entered into the hospital's IVF or G.I.F.T. program, the woman begins taking injections of fertility drugs daily from the second day of her menstrual cycle. This continues for approximately seven to ten days. During this time her cycle is monitored closely by ultrasound and blood tests regularly.

A laparoscopy is performed usually between day ten and twelve. In this "band aid" surgery under general anesthesia, a small incision is made and a hollow needle retrieves the maturing egg or eggs.

The eggs are placed in a culture media "in vitro," and a semen specimen is obtained from the husband. Once the eggs are fertilized, the resulting embryos are transferred back into the uterus, approximately two days after the laparoscopy. Embryo transfer is a non-surgical procedure, not unlike a pelvic examination.

In all, a time commitment of two weeks is necessary. It is desirable to have all ultrasound and blood tests performed at Century City Hospital. Those coming from far away need to find nearby accommodations to ensure that they can be at the hospital for testing before 8 a.m. almost every day.

Two weeks following embryo transfer, a blood sample is taken to determine if pregnancy has occurred and if it is proceeding normally. It may be necessary to take progesterone or other hormones during this time to prepare the uterine lining for pregnancy.

THE G.I.F.T. PROCEDURE

G.I.F.T. (Gamete Intra-Fallopian Transfer), first introduced in 1984 and used very successfully, especially for unexplained infertility, differs from IVF in that the sperm and unfertilized eggs, after retrieval, are inserted into the healthiest part of the fallopian tube so that the actual fertilization takes place "naturally" inside the mother's body.

The first weeks of taking fertility drugs, ultrasound monitoring and egg and sperm retrieval are the same as in the IVF procedure. However, the eggs and sperm are not put in a dish for fertilization. Rather, the eggs are retrieved by laparoscopy and examined under a microscope for maturity. The husband's sperm, collected two hours before the procedure, is prepared in the laboratory. After careful observation and confirmation of viability, the sperm and eggs are transferred with a special catheter into the fallopian tube (ampulla). The ampulla region of the tube is where fertilization occurs in "normal" conceptions, thus allowing for fertilization to occur as naturally as possible. Pregnancy testing two weeks later is the same as in the IVF procedure.

HAVE YOUR BABY CLOSE TO HOME

Once the pregnancy is proceeding normally, we encourage patients to return to the care of their own physician at whatever hospital is most convenient to their home. Our patients often feel most comfortable having their own physician for the delivery. To better coordinate Century City Hospital's services with the patient's doctor, that doctor is invited to the hospital to participate in the embryo transfer.

RATE OF SUCCESS

From currently available information, the chances of achieving pregnancy through in vitro fertilization and embryo transfer range anywhere from 5% to 30% per attempt. The likelihood of success is dependent to a great degree on such variables as the couple's age and the initial reasons for the couple's infertility. It has been estimated that the "success rate per try" in natural conception is between 25% and 30%. Even in nature, egg and sperm sometimes meet without fertilization, or development begins and then stops.

In nature, about 3% of all births have some malformations, and according to a special committee appointed by the Secretary of Health, Education and Welfare, there is no evidence to suggest that in vitro births would be any higher or lower than this statistic. In vitro fertilization/embryo transfer is no longer considered an investigational procedure.

There will be some risks and discomforts during the procedures which patients need to be aware of. Small bruises often occur from blood drawing. Fertility medications may over-stimulate the ovaries which may cause discomfort. Ovarian cysts may develop.

Laparoscopy may cause bleeding, infection or injury to the abdominal organs. General anesthesia contains some risks and discomfort. There are no known risks associated with ultrasound.

During the embryo transfer, discomfort, possible bleeding and infection may occur. Ectopic (tubal) pregnancy is possible, requiring surgery. Many personal physicians consider an IVF pregnancy to be high risk, and prefer to deliver by Cesarean Section. Check with your own doctor.

If more than one embryo is not transferred, the chances of achieving pregnancy drop dramatically. However, when multiple embryos are transferred, multiple births (twins, triplets) become more possible.

* * *

There is a certain amount of psychological and emotional stress associated with this procedure. If requested by the physician, a psychosocial evaluation and screening will be performed by an affiliated psychiatrist to help the couple anticipate emotional problems.

Support group sessions (not group therapy) are also offered to couples in order to help them share and hear mutual concerns and experiences.

Despite all the concerns, the joy experienced by finally-fertile couples seem to make all the efforts worthwhile. We're excited to be involved in enabling many couples to experience that once-in-a-lifetime wonder.

⁂

FEE AND INSURANCE COVERAGE

Fees are collected at the beginning of the patient's cycle. Cost breakdowns are available upon request and are separated by hospital, physician, laboratory charges, etc. A pro-rated, 30-day refund for interrupted cycles is built into the program.

Because many insurance plans do not cover these procedures, couples are personally responsible for all expenses. The hospital will provide all necessary forms if the patients wish to file for reimbursement.

Underground parking is free at Century City Hospital when you come for scheduled appointments, testing and treatment. Be sure to ask for parking validation.

* * *

CONFIDENTIALITY AND PUBLICITY

All information obtained about patients by the hospital or physicians is, of course, confidential. Any statistics or other information released will be general. Any specific information used in professional publications will conceal identities.

We request our patients refrain from granting interviews or having contact with the news media. Our public relations department is available for consultation and assistance.

For more information, call the IVF/ET Coordinator between 9 a.m. and 4 p.m., weekdays: (213) 201-6619

"Dreams are necessary to life." —Anaïs Nin

CENTER FOR
REPRODUCTIVE
MEDICINE
CENTURY CITY HOSPITAL

Many fertile and infertile couples share an important trait: the dream of bringing a new life into the world. But for the couple unable to conceive, that dream is often frustrated by a seemingly endless string of disappointments.

Now, instead of letting disappointment turn to despair, let the Center for Reproductive Medicine give new life to the dream.

The Center for Reproductive Medicine of Century City Hospital stands at the forefront of reproductive biology, offering resources that match the dreams of the infertile couple.

There may be a lot of reasons why pregnancy isn't working for the one out of six couples unable to conceive. Here, fertility experts coordinate care to thoroughly investigate and then confirm the source of the problem. They are then able to offer one of the nation's most comprehensive arrays of treatment options.

In the beginning.

If the cause of infertility is unknown, trial and error treatments can sap the resources of the hopeful couple. That's why, at the Center for Reproductive Medicine, trial and error gives way to tried and true. Physicians specializing in reproductive biology and therapy carefully confirm the problem's cause through a variety of proven tests.

The cause may lie in the ovaries or uterus. The fallopian tubes may be blocked or not functioning properly. There may be systemic disease preventing pregnancy.

Or perhaps the origin is not to be found in the woman at all. In such a case, pioneering expertise in andrology—the male equivalent of gynecology—comes into play. Center specialists in this relatively new discipline offer comprehensive testing of the male through computerized semen analysis, sperm penetration assays and immunological studies.

Finding the source is the beginning of finding the solution. And the Center for Reproductive Medicine offers a solution for virtually every unique, individual situation.

Making the dream come true.

There are no simple textbook approaches to bringing pregnancy to the infertile couple. And there's no guarantee of success. But because the Center offers a variety of treatment programs, more couples than ever before have the potential to realize their dream. In fact, it's come true for over one in five couples, based on clinical pregnancy rate per surgical procedure.

Here, procedure matches need.

If in vitro fertilization is called for, eggs collected from the woman are fertilized with the husband's sperm and then transferred to the uterus, where pregnancy can be established. Egg retrieval is facilitated through an advanced ultrasound procedure that requires no general anesthesia or surgery.

When "natural" fertilization is possible, gamete intra-fallopian transfer (G.I.F.T.) allows the implantation of a couple's own harvested sperm and single, unfertilized egg at the entrance of an oviduct.

If the uterus lacks biological integrity, the IVF surrogate pregnancy program can provide the opportunity for pregnancy while keeping genetic integrity intact. Using the sperm and eggs of the biological couple, a carefully screened surrogate mother is implanted with the in vitro fertilized embryo. Carried to term, the child is genetically the couple's. Not the surrogate's.

Additionally, the Center offers cryopreservation of sperm and embryos, a variety of laser surgical procedures including tuboplasty and microscopic reversal of vasectomy, plus access to donor semen and counseling for psychosexual dysfunction. Physicians at the Center also have complete knowledge of all known fertility drugs — even the most recently introduced — and are able to put them to optimum use through a program of careful monitoring and titration.

And because the dream of a new life isn't limited solely to younger people, the Center for Reproductive Medicine does not limit its resources to women under 40. Age need not be a barrier. And the Center won't quit trying until the couple does.

All services are coordinated with the referring physician, who is kept fully informed as the program progresses. Once pregnancy is proceeding normally, patients are encouraged to return to the care of their personal OB/GYN.

A nurturing environment.

Because of the complexity of reproductive biology, the Center for Reproductive

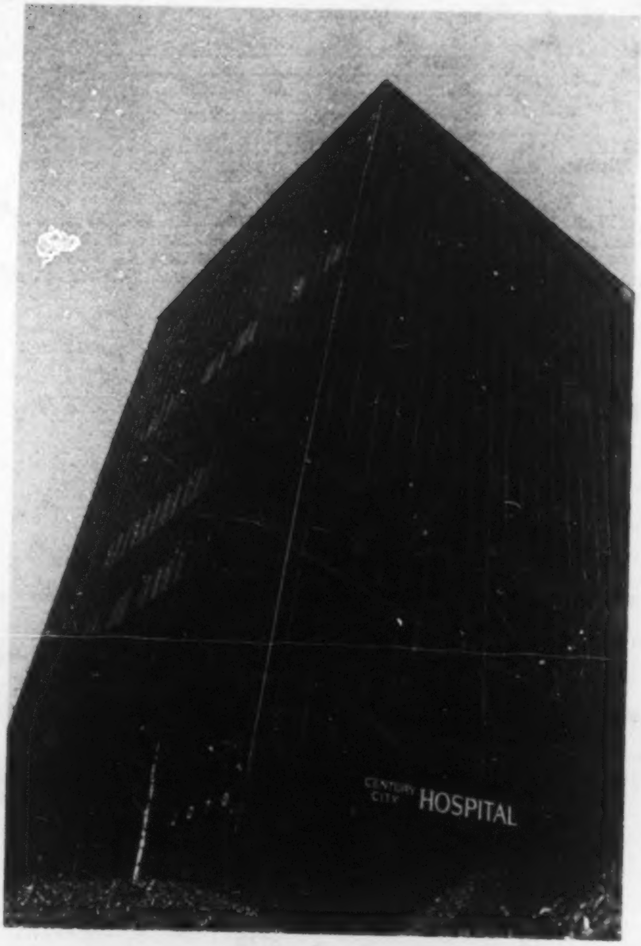
Medicine coordinates the concerted efforts of a variety of physicians in an environment conducive to total care. These professionals comprise experienced representatives from the Departments of Gynecology, Andrology, Endocrinology, Nursing, Pathology, Urology, Reproductive Biology and Psychiatry, supported by the Executive Director, the Medical Advisory Committee and the Medical Director.

At the Center, total care also means personalized care. Couples find the environment individualized and complete. Physicians, nurses and counselors accommodate the special needs of each case, spending as much concerned time with the couple as necessary. Dignity, respect and confidentiality go hand in hand with advanced technology.

Underscoring that dignity and respect is the Center's commitment to the couple's timely desires. The waiting list for any test or procedure is minimal. And once beginning the program, procedures can be performed any time, day or night, weekdays or weekends. The Center for Reproductive Medicine is ready.

What our dreams tell us.

Often, we can achieve in a dream what seems impossible in life. But just as often, dreams give us a new vision of the possible. The Center for Reproductive Medicine exists to share that vision with couples who don't believe in failure. So we can help bring the dream to life.


CENTURY CITY HOSPITAL

THE CENTER FOR REPRODUCTIVE MEDICINE
CENTURY CITY HOSPITAL
2070 Century Park East
Los Angeles, CA 90067
(213) 201-6619

IVF/GIFT SURVEY

CLINIC NAME: AMI - South Bay Hospital - IVF Center
ADDRESS: 514 So. Prospect Ave.
Redondo Beach, Ca. 90277

CONTACT PERSON: David R. Meldrum, M.D.
PHONE NUMBER: (213) 318-4741

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/10/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based x
   (c) University based ______
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   (a) Physicians 0
   (b) Laboratory Scientists (PhDs) 0
   (c) Nurses 4
   (d) Embryo Lab Technicians/Technologists 2
   (e) Other Lab Technicians/Technologists 2
   (f) Radiology (Ultrasound) Technicians 0
   (g) Psychologists/Counselors 1
   (h) Secretaries 1
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF January 1987 GIFT March 1987

9. How many different patients were stimulated?
1987 IVF 91 1988 IVF 119
GIFT 3 GIFT 3

10. How many stimulation cycles were performed?
1987 IVF 115 1988 IVF 147
GIFT 3 GIFT 3

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 99 1988 122

How many embryo transfer cycles were performed?
1987 98 1988 120

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 3 1988 3

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 75 82 % 1988 IVF 94 79 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 21 23 % 1988 IVF 33 28 %
GIFT 0 0 % GIFT 2 67 %
(c) Male infertility:
1987 IVF 17 19 % 1988 IVF 16 13 %
GIFT 0 0 % GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 4 4 % 1988 IVF 5 4 %
GIFT 3 100 % GIFT 1 33 %
(e) Other (explain): anovulation
1987 IVF 2 2 % 1988 IVF 3 3 %
GIFT 0 0 % GIFT 0 0 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 12 13 % 1988 IVF 23 19 %
GIFT 0 0 % GIFT 0 0 %
(b) 31-35:
1987 IVF 26 29 % 1988 IVF 40 34 %
GIFT 0 0 % GIFT 1 33 %
(c) 36-40:
1987 IVF 51 56 % 1988 IVF 52 44 %
GIFT 3 100 % GIFT 1 33 %

(d) 41-45:
1987 IVF 2 2 % 1988 IVF 5 4 %
GIFT 0 0 % GIFT 1 33 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 31 1988 IVF 36
GIFT 1 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 23* 1988 IVF 9
GIFT 1 GIFT 1
*2 more women delivered live infants from frozen embryos

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ____ 1988 IVF 20
GIFT ____ GIFT ____

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 3
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 8 35 % 6 twins, 2 triplets
GIFT 0 ___ % ____________

1988 IVF 3 33 % 2 twins, 1 triplet
GIFT 0 ___ % ____________

21. What are the qualifications of the director of the embryo laboratory? 1 year experience in ovum transfer. 4½ years experience in IVF

22. Who supervises the laboratory director? Dr. Meldrum

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
CAP

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
- **(a) Physicians** ______
- **(b) Laboratory scientists (PhDs)** ______
- **(c) Embryo laboratory technicians/technologists** ______
- **(d) Nurses** ______
- **(e) Other (explain)** ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

This program is a continuation of the UCLA IVF program started by Dr. Meldrum in September 1983, with the same laboratory director since 1984. The clinical pregnancy rate has been remarkably stable at approximately 30% (Fertil Steril 48:86, 1987) in spite of an increasing proportion of patients who have had prior IVF cycles without success, an increasing proportion of patients over 40, and a low rate of cancelled stimulations. Many of our patients have antisperm antibodies but are listed under their other etiology or as unexplained. All other treatments that the patients are willing to try, including superovulation, are exhausted before going on to IVF or GIFT. Volume is moderate, so that maximal attention can be directed toward each individual couple. Since the center is devoted to IVF and infertility, organization is specifically adapted to these special procedures.

In women under 40 during 1987 and 88, our clinical pregnancy rate has been 33% with a term delivery rate of 26%, not including frozen embryo pregnancies from those cycles.

IVF/GIFT SURVEY

CLINIC NAME: In Vitro Fertilization
ADDRESS: Northridge Hospital Medical Center
18300 Roscoe Boulevard
Northridge, California 91328

CONTACT PERSON: Dr. David W. Richards
PHONE NUMBER: 818-885-5420

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the never clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/ /88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 6

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 6

6. How many other professionals participate in your clinic?
   - (a) Physicians 2
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses ______
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists ______
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors ______
   - (h) Secretaries ______
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 4 1/2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF June 84 GIFT May 86

9. How many different patients were stimulated?
1987 IVF 116 1988 IVF 77
GIFT 7 GIFT 26

10. How many stimulation cycles were performed?
1987 IVF 257 1988 IVF 185
GIFT 14 GIFT 38

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 180 1988 152

How many embryo transfer cycles were performed?
1987 149 1988 139

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 11 1988 30

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 160 62% 1988 IVF 135 75%
GIFT 0 ___% GIFT 0 0%
(b) Endometriosis:
1987 IVF 24 9% 1988 IVF 14 8%
GIFT 2 14% GIFT 13 34%
(c) Male infertility:
1987 IVF 38 15% 1988 IVF 17 10%
GIFT 1 7% GIFT 3 9%
(d) Unexplained infertility:
1987 IVF 35 14% 1988 IVF 13 7%
GIFT 11 79% GIFT 22 58%
(e) Other (explain): ___
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 1 ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 27 23% 1988 IVF 17 23%
GIFT 4 57% GIFT 7 31%
(b) 31-35:
1987 IVF 54 47% 1988 IVF 28 38%
GIFT 3 43% GIFT 9 39%
(c) 36-40:
1987 IVF 31 27% 1988 IVF 23 32%
GIFT 0 ___% GIFT 5 22%

(d) 41-45:
1987 IVF 4 3 % 1988 IVF 5 7 %
GIFT 0 __ % GIFT 2 8 %

(e) >45:
1987 IVF 0 __ % 1988 IVF 0 __ %
GIFT 0 __ % GIFT 0 __ %

16. How many clinical pregnancies were produced?
1987 IVF 32 1988 IVF 20
GIFT 1 GIFT 11

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 24 1988 IVF 26
GIFT 0 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 12
GIFT 0 GIFT 8

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 2

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 5 21 % Twins
GIFT 0 0 %

1988 IVF 6 27 % Twins
GIFT 1 13 % Triplets

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Reproductive Physiology and a Post-Doctoral Fellow in Reproductive Medicine - IVF

22. Who supervises the laboratory director? Hospital Administration

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? NO
If the answer is yes, how many individuals in the following specialties have been trained?
    - (a) Physicians ________
    - (b) Laboratory scientists (PhDs) ________
    - (c) Embryo laboratory technicians/technologists ______
    - (d) Nurses ________
    - (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The Northridge In Vitro Fertilization Program is an open program in which at present 8 different Private Physicians use the In Vitro Fertilization Laboratory at Northridge Hospital Medical Center.

[redacted]

IVF/GIFT SURVEY

CLINIC NAME: HUNTINGTON REPRODUCTIVE CENTER

ADDRESS: 39 CONGRESS ST - SUITE 202
PASADENA, CALIFORNIA 91105

CONTACT PERSON: PAULO SERAFINI / JOEL BATZOFIN

PHONE NUMBER: 818-4409161

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? DEC 1988
2. Does your clinic perform IVF/GIFT treatments? YES
   (If the answer is no, there is no need to complete the remainder of the questionnaire.)
3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) ________
4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? TWO
5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? TWO
6. How many other professionals participate in your clinic?
   - (a) Physicians ONE
   - (b) Laboratory Scientists (PhDs) NONE
   - (c) Nurses THREE
   - (d) Embryo Lab Technicians/Technologists TWO
   - (e) Other Lab Technicians/Technologists ONE
   - (f) Radiology (Ultrasound) Technicians NONE
   - (g) Psychologists/Counselors ONE
   - (h) Secretaries THREE
   - (i) Other (specify) ________
7. How many years has your infertility clinic been in operation? SINCE JUNE 1988
8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 6/1/88 GIFT 6/1/88

9. How many different patients were stimulated?
1987 IVF / 1988 IVF 61
GIFT / GIFT 27

10. How many stimulation cycles were performed?
1987 IVF / 1988 IVF 68
GIFT / GIFT 28

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 / 1988 53

How many embryo transfer cycles were performed?
1987 / 1988 47

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 / 1988 23

13. What were the number and percentage of patients on IRB approved research protocols?
1987 / ___% 1988 100 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___/___% 1988 IVF 70,5 %
GIFT ___/___% GIFT ZERO %
(PER PATIENT STIMULATED)
(b) Endometriosis:
1987 IVF ___/___% 1988 IVF 3,2 %
GIFT ___/___% GIFT 29,6 %
(c) Male infertility:
1987 IVF ___/___% 1988 IVF 26,2 %
GIFT ___/___% GIFT 37,0 %
(d) Unexplained infertility:
1987 IVF ___/___% 1988 IVF ZERO %
GIFT ___/___% GIFT 14,8 %
(e) Other (explain): ADHESIONS, POLYCYSTIC OVARIES
1987 IVF ___/___% 1988 IVF ___%
GIFT ___/___% GIFT 18,5 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___/___% 1988 IVF 3,3 %
GIFT ___/___% GIFT 3,7 %
(b) 31-35:
1987 IVF ___/___% 1988 IVF 39,4 %
GIFT ___/___% GIFT 59,3 %
(c) 36-40:
1987 IVF ___/___% 1988 IVF 31,1 %
GIFT ___/___% GIFT 18,5 %

(d) 41-45:
1987 IVF ___ ___% 1988 IVF 26.2 %
GIFT ___ ___% GIFT 14.8 %

(e) >45:
1987 IVF ___ ___% 1988 IVF Zero %
GIFT ___ ___% GIFT ZERO %

16. How many clinical pregnancies were produced?
1987 IVF ____ 1988 IVF 13
GIFT ____ GIFT 10 (TEN)

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ____ 1988 IVF —
GIFT ____ GIFT —

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ____ 1988 IVF 8
GIFT ____ GIFT 3

19. How many ectopic pregnancies resulted?
1987 IVF ____ 1988 IVF Zero
GIFT ____ GIFT 2 (TWO)

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ____________
GIFT ___ ___% ____________

1988 IVF ___ ___% NONE
GIFT ___ ___% ONE MULTIPLE – (TRIPLETS)

21. What are the qualifications of the director of the embryo laboratory? QUALIFIED TRAINING WITH /UNDER DIRECTION OF SCIENTISTS FOR YEARS.

22. Who supervises the laboratory director? PHYSICIANS

23. Does the clinic participate in an external laboratory proficiency testing program? YES
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic PHYSICIANS a member of the Society for Assisted Reproductive Technology? YES

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians _______
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists ONE
    (d) Nurses ONE
    (e) Other (explain) _______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

HUNTINGTON REPRODUCTIVE CENTER WAS ESTABLISHED IN MAY 1988 BY THE REPRODUCTIVE ENDOCRINOLOGISTS DRS PAULO SERAFINI AND JOEL BATZOFIN. PRIOR TO THAT THE DOCTORS AND LABORATORY PERSONNEL WERE ASSOCIATED WITH THE IVF TEAM OF DR RICHARD MARAS. AND CEDARS-SINAI MEDICAL CENTER. IN JULY 1988, DR WILLIAM BLANK A UROLOGIST/MALE INFERTILITY SPECIALIST JOINED HUNTINGTON REPRODUCTIVE CENTER. DR BLANK IS AN EXPERT IN TREATMENT OF SPINAL CORD INJURED MEN WITH ELECTRICAL ASSISTED TECHNIQUES AND ONGOING PREGNANCIES HAVE BEEN ESTABLISHED.

RESULTS OF 1989 IVF AND GIFT:

GIFT - 18 EGG RECOVERIES - (ALL AGES) - 11 ONGOING PREGNANCIES (61.1%)

IVF - 20 EGG RECOVERIES RESULTED IN 17 EMBRYO TRANSFERS (ALL AGES)
- 5 ONGOING PREGNANCIES (29.4%)

RECEIVED
FEB 3 1989
Hon. Ron Wyden

IVF/GIFT SURVEY

CLINIC NAME: Northern California Fertility Center
ADDRESS: 87 Scripps Drive Suite 202
Sacramento, CA 95825

CONTACT PERSON: Bette Sehnert
PHONE NUMBER: (916) 929-3596

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 10-31-88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private x
   - (b) Community hospital based ____
   - (c) University based ____
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? none

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians 3
   - (b) Laboratory Scientists (PhDs) ____
   - (c) Nurses 9
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians ____
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1988

9. How many different patients were stimulated?
1987 IVF 46 1988 IVF 26
GIFT 0 GIFT 22

10. How many stimulation cycles were performed?
1987 IVF 76 1988 IVF 42
GIFT 0 GIFT 26

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 46 1988 30

How many embryo transfer cycles were performed?
1987 41 1988 26

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 10

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0 % 1988 ___ 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 26 57 % 1988 IVF 19 73%
GIFT N/A ___ % GIFT 2 9 %
(b) Endometriosis:
1987 IVF 5 11 % 1988 IVF 5 19 %
GIFT N/A ___ % GIFT 5 23 %
(c) Male infertility:
1987 IVF 3 7 % 1988 IVF 0 0 %
GIFT N/A ___ % GIFT 4 18 %
(d) Unexplained infertility:
1987 IVF 6 13 % 1988 IVF 0 0 %
GIFT N/A ___ % GIFT 10 45 %
(e) Other (explain): Pelvic Adhesions - IVF; Premature Ovarian Failure GIFT
1987 IVF 6 13 % 1988 IVF 2 8 %
GIFT N/A ___ % GIFT 1 5 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 11 24 % 1988 IVF 4 15 %
GIFT N/A ___ % GIFT 1 5 %
(b) 31-35:
1987 IVF 14 30 % 1988 IVF 14 54 %
GIFT N/A ___ % GIFT 7 32 %
(c) 36-40:
1987 IVF 18 39 % 1988 IVF 8 31 %
GIFT N/A ___ % GIFT 13 59 %

(d) 41-45:
1987 IVF 3 7 % 1988 IVF 0 0 %
GIFT N/A ___ % GIFT 1 5 %

(e) >45:
1987 IVF ___ 0 % 1988 IVF ___ 0 %
GIFT ___ 0 % GIFT ___ 0 %

16. How many clinical pregnancies were produced?
1987 IVF 5 1988 IVF 6
GIFT N/A GIFT 4

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 5 1988 IVF 0
GIFT N/A GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 4
GIFT N/A GIFT 2

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT N/A GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 40 % 1 2-delivered; 1 twin pregnancy, 1 SAB, 1 delivere
GIFT N/A ___ % ___

1988 IVF 1 17 % Triplet - 3 ongoing
GIFT 2 50 % triplet - 3 delivered; 1 twin - 2 SAB

21. What are the qualifications of the director of the embryo laboratory? M.S. training in embryo micromanipulation, culture and transfer. Continuing education in IVF/GIFT; Cooperation and on-sight training at various IVF laboratories.

22. Who supervises the laboratory director? Program director

23. Does the clinic participate in an external laboratory proficiency testing program? Our clinical lab does; the IVF lab does not at this time
If the answer is yes, please specify which program. Clinical lab -CAP; The IVF lab participates with other IVF programs in our area to self-regulate and provide support for laboratory services.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? NO

26. Is the clinic a member of the Society for Assisted Reproductive Technology? application pending

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ______
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ______
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Forest Fertility Center
ADDRESS: 3110 Forest Ave
San Jose, Ca. 95128

CONTACT PERSON: Vincent Nola MD. or Peter di Donato MD.
PHONE NUMBER: 408-288-5583

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following date is current through what date? 12/12/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ______
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? None

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   - (a) Physicians 1
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 2
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 4 yrs As Forest Fertility Center. Vincent Nola, M.D. has practiced OB-Gyn-Infertility for 27 years.

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1988 GIFT 1986

9. How many different patients were stimulated?
1987 IVF 0 1988 IVF 7
GIFT 8 GIFT 1 (1 combined IVF-GIFT procedure)

10. How many stimulation cycles were performed?
1987 IVF 0 1988 IVF 9
GIFT 8 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 0 1988 9

How many embryo transfer cycles were performed?
1987 0 1988 9

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 8 1988 1 (As part of a combined procedure)

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 0 0% 1988 IVF 5 62%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 0 0% 1988 IVF 2 25%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 0 0%
(d) Unexplained infertility:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 0 0%
(e) Other (explain): DES
1987 IVF 0 ___% 1988 IVF 1 12%
GIFT 0 ___% GIFT 0 0%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 0% 1988 IVF ~~6~~ ~~75~~%
GIFT 0 0% GIFT ___ ___%
(b) 31-35:
1987 IVF 0 0% 1988 IVF 6 75%
GIFT 3 37.5% GIFT ___ ___%
(c) 36-40:
1987 IVF 0 0% 1988 IVF 2 25%
GIFT 5 62.5% GIFT ___ ___%

(d) 41-45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

(e) >45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF ___ 1988 IVF 1
GIFT 1 GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ___
GIFT ___ ___% ___

1988 IVF ___ ___% ___
GIFT ___ ___% ___

21. What are the qualifications of the director of the embryo laboratory? B.S., PA-C (Physician Assistant - Certified)
University of Wisconsin IVF Course AFS - Advanced Course in IVF

22. Who supervises the laboratory director? PhD. embryologist

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    - (a) Physicians ________
    - (b) Laboratory scientists (PhDs) ________
    - (c) Embryo laboratory technicians/technologists ________
    - (d) Nurses ________
    - (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Dear Congressman Wyden,

We strongly support your efforts to protect couples seeking treatment for infertility.

Sincerely yours,

Vincenzo [illegible], M.D.
[illegible] di Donato, P.A.-C.

IVF/GIFT SURVEY

CLINIC NAME: UCSF FERTILITY ASSOCIATES
ADDRESS: UNIV. OF CALIF SAN FRANCISCO
DEPT OF OB/GYN & REPRODUCTIVE SCIENCES
BOX 0132, ROOM M-1489
SAN FRANCISCO, CA 94143
CONTACT PERSON: MARY C. MARTIN, M.D.
PHONE NUMBER: (415) 476-2224

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12-31-88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    (a) Private ______
    (b) Community hospital based ______
    (c) University based X
    (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
    (a) Physicians 4-6 FELLOWS PER YEAR, 1 HOUSE OFFICER PER MONTH
    (b) Laboratory Scientists (PhDs) 1 PhD, 1 MSc.
    (c) Nurses 2
    (d) Embryo Lab Technicians/Technologists 2
    (e) Other Lab Technicians/Technologists RIA LAB: 4-5
    (f) Radiology (Ultrasound) Technicians ______
    (g) Psychologists/Counselors 1
    (h) Secretaries 2
    (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1987

9. How many different patients were stimulated?
1987 IVF 140 1988 IVF 158
GIFT 6 GIFT 4

10. How many stimulation cycles were performed?
1987 IVF 194 1988 IVF 215
GIFT 6 GIFT 4

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 124 1988 142

How many embryo transfer cycles were performed?
1987 106 1988 124

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 6 1988 4

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0% 1988 61 28.3%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 139 74% 1988 IVF 137 64%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 30 16% 1988 IVF 51 24%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF 52 28% 1988 IVF 47 22%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF 24 13% 1988 IVF 41 19%
GIFT 6 100% GIFT 4 100%
(e) Other (explain): DES
1987 IVF 6 3% 1988 IVF 6 3% (SOME PATIENTS WITH
GIFT ___ ___% GIFT ___ ___% MORE THAN ONE FACTOR)

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 13 7% 1988 IVF 13 6% OF CYCLES
GIFT 0 0% GIFT 0 0%
(b) 31-35:
1987 IVF 69 36% 1988 IVF 74 34%
GIFT 2 33% GIFT 2 50%
(c) 36-40:
1987 IVF 100 51% 1988 IVF 121 56%
GIFT 2 33% GIFT 2 50%

(d) 41-45:
1987 IVF 13 7 % 1988 IVF 7 3 %
GIFT 2 33 % GIFT 0 0 %

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 15 1988 IVF 30
GIFT 2 GIFT 4

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 11 1988 IVF 6
GIFT 1 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 20
GIFT 0 GIFT 2

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 0
GIFT 1 GIFT 2

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 4 27 % OF PREG. ESTABLISHED) - 2 TRIPLETS, 2 TWINS
GIFT 0 0 %
1988 IVF 6 20 % (OF PREG. ESTABLISHED) 1 QUAD, 2 TRIPLETS, 3 TWINS
GIFT 1 25 % 1 TWIN

21. What are the qualifications of the director of the embryo laboratory? TRAINED AS A CELL BIOLOGIST, RESEARCH EXPERIENCE WITH EMBRYOS AND 8 YEARS IN THE FIELD OF IVF

22. Who supervises the laboratory director? PROGRAM DIRECTOR

23. Does the clinic participate in an external laboratory proficiency testing program? YES
If the answer is yes, please specify which program.
RIA LAB IS A LICENSED LABORATORY

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? YES

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? YES

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 8
    (b) Laboratory scientists (PhDs) 1
    (c) Embryo laboratory technicians/technologists ____
    (d) Nurses 1
    (e) Other (explain) ____

28. Please provide any comments you may have on your clinic's patient population, treatments, or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Pacific Fertility Center
ADDRESS: 2100 Webster Street #920
San Francisco, Ca 94115

CONTACT PERSON: Geoffrey Sher MD
PHONE NUMBER: (415)- 923-3344

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? Yes -
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ✓
   - (b) Community hospital based _______
   - (c) University based _______
   - (d) Other (explain) _______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? I

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians —
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 4
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists —
   - (f) Radiology (Ultrasound) Technicians —
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 3
   - (i) Other (specify) 1- CLINICAL COORDINATOR

7. How many years has your infertility clinic been in operation? I

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF JANUARY-1988 GIFT —

9. How many different patients were stimulated?
1987 IVF NAP 1988 IVF 84
GIFT NAP GIFT —

10. How many stimulation cycles were performed?
1987 IVF NAP 1988 IVF 123
GIFT NAP GIFT —

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 NAP 1988 102

How many embryo transfer cycles were performed?
1987 NAP 1988 96

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 NAP 1988 —

13. What were the number and percentage of patients on IRB approved research protocols?
1987 — % 1988 — %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF NAP % 1988 IVF 45 - 53 %
GIFT NAP % GIFT — %
(b) Endometriosis:
1987 IVF NAP % 1988 IVF 8 - 10 %
GIFT NAP % GIFT — %
(c) Male infertility:
1987 IVF NAP % 1988 IVF 25 · 30 %
GIFT NAP % GIFT — %
(d) Unexplained infertility:
1987 IVF NAP % 1988 IVF 6 - 7 %
GIFT NAP % GIFT — %
(e) Other (explain): ____
1987 IVF NAP % 1988 IVF — %
GIFT NAP % GIFT — %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF NAP % 1988 IVF 8 8 %
GIFT NAP % GIFT — %
(b) 31-35:
1987 IVF NAP % 1988 IVF 21 - 20 %
GIFT NAP % GIFT — %
(c) 36-40:
1987 IVF NAP % 1988 IVF 60 - 59 %
GIFT NAP % GIFT — %

(d) 41-45:
1987 IVF NAP % 1988 IVF 13 13 %
GIFT NAP % GIFT — — %

(e) >45:
1987 IVF NAP % 1988 IVF — — %
GIFT NAP % GIFT — — %

16. How many clinical pregnancies were produced?
1987 IVF } NAP 1988 IVF 28
GIFT GIFT —

17. How many women delivered live infants from IVF/GIFT?
1987 IVF } NAP 1988 IVF 6
GIFT GIFT —

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF } NAP 1988 IVF 16
GIFT GIFT —

19. How many ectopic pregnancies resulted?
1987 IVF } NAP 1988 IVF 1
GIFT GIFT —

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF NAP % —
GIFT NAP % —

1988 IVF 2 30 % 1 set twins, 1 set Quadruplets
GIFT — %

21. What are the qualifications of the director of the embryo laboratory? pHD

22. Who supervises the laboratory director? GEOFFREY SHER MD

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program. —

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (_Fertility and Sterility_, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? NO
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians —
    (b) Laboratory scientists (PhDs) —
    (c) Embryo laboratory technicians/technologists —
    (d) Nurses —
    (e) Other (explain) —

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

) Clinical Pregnancy & Anticipated Birth Rates!

age groups

	women Less than 36yrs	women 36 to 41yrs.	women 41yrs - 46yrs	ALL ages [overall]
linical Pregnancies				
Per egg Retrieval	35%	25%	15%	27%
per embryo transfer	36%	26%	20%	29%
per woman	46%	28%	25%	33%
Anticipated Births				
per egg Retrieval	28%	18%	10%	21%
per embryo transfer	29%	19%	13%	22%
per woman	32%	20%	16%	26%

Definitions

(a) Clinical Pregnancy is an ultrasound confirmation of a gestational SAC

(b) Anticipated Birth = all viable ongoing ultrasound confirmed pregnancies + the total number of women who gave birth to healthy babies

---

② - The Program at Pacific Fertility Center performed 7 combination IVF + GIFT procedures — 3 women achieved clinical pregnancies [43%]

— GIFT is not perfomed as an isolated Procedure in our Program.

IVF/GIFT SURVEY

CLINIC NAME: Reproductive Endocrinology and Infertility Clinic
ADDRESS: Department of Gynecology and Obstetrics
Stanford University
Stanford, CA 94305

CONTACT PERSON: Emmet J. Lamb, MD
PHONE NUMBER: 415-723-6950

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the never clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Dec 6/1988

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2 + *

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2 + *

6. How many other professionals participate in your clinic?
   - (a) Physicians 1 *Trained as Reproductive endocrinologist but not eligible for ABOG [illegible]
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 4
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors 1 part time
   - (h) Secretaries ______
   - (i) Other (specify) 1 secretary part time

7. How many years has your infertility clinic been in operation? 3

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF November 1985 GIFT July 1985

9. How many different patients were stimulated?
1987 IVF 93 1988 IVF 45
GIFT 7 GIFT 9

10. How many stimulation cycles were performed?
1987 IVF 121 1988 IVF 64
GIFT 10 GIFT 14

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 83 1988 49

How many embryo transfer cycles were performed?
1987 65 1988 42

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 6 1988 10

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:

This data is not complete in our microcomputer. We will forward it when available. Data for 1986 is available.

(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ___________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:

See note for #14

(a) <31:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 4 1988 IVF 3
GIFT 2 GIFT 2

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF 0
GIFT 1 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 2
GIFT ___ GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births? see attached percentages.
1987 IVF ___ ___% one singleton, two sets of twins
GIFT 1 ___% Twin.
1988 IVF ___ ___% {one continuing at 14 weeks twins.
{one continuing at 19 weeks. twins – reduced from quads.
GIFT ___ ___% 1 continuing as singleton at 15 weeks.

21. What are the qualifications of the director of the embryo laboratory? See attached.

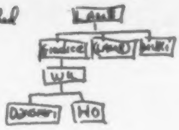
22. Who supervises the laboratory director? *

23. Does the clinic participate in an external laboratory proficiency testing program? yes
If the answer is yes, please specify which program.
american Society of Clinical Pathologists

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? yes, until 7-1-88 when fellowship was discontinued voluntarily.

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

* See attached



26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes If the answer is yes, how many individuals in the following specialties have been trained?
    - (a) Physicians 3
    - (b) Laboratory scientists (PhDs) ______
    - (c) Embryo laboratory technicians/technologists 2
    - (d) Nurses 3
    - (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

STANFORD REI CLINIC

		1985	1986	1987	1988	TOTAL
CYCLES (IVF)						
	CYCLES STARTED	6	147	121	64	338
						0
	LH SURGE	1	21	9	2	33
	POOR RESPONSE	1	22	21	8	52
	OTHER	1	3	8	5	17
	SUBTOTAL	3	46	38	15	102
	% ABANDONED	50.0%	31.3%	31.4%	23.4%	30.2%
						0
	HARVESTS, NUMBER	3	101	83	49	236
	NO EGGS		5	5	3	13
	NO FERTILIZATION	1	25	13	4	43
						0
	EMBRYO TRANSFER, NUM	2	71	65	42	180
	NOT PREGNANT	2	57	60	39	158
	PREGNANT	0	14	5	3	22
	BIOCHEMICAL		2	1		3
	ABORTION			1	1	2
	ECTOPIC		1			1
	VIABLE		11	3	2	16
						0
ALL	PER CENT OF E.T.'S	0.0%	19.7%	7.7%	7.1%	12.2%
	PER CENT OF HARVESTS	0.0%	13.9%	6.0%	6.1%	9.3%
	PER CENT OF CYCLES	0.0%	9.5%	4.1%	4.7%	6.5%
						0
CLINCICAL	PER CENT OF E.T.'S	0.0%	16.9%	6.2%	7.1%	10.6%
	PER CENT OF HARVESTS	0.0%	11.9%	4.8%	6.1%	8.1%
	PER CENT OF CYCLES	0.0%	8.2%	3.3%	4.7%	5.6%
VIABLE	PER CENT OF E.T.	0.0%	15.5%	4.6%	4.8%	8.9%
	PER CENT OF HARVESTS	0.0%	10.9%	3.6%	4.1%	6.8%
	PER CENT OF CYCLES	0.0%	9.5%	4.1%	4.7%	6.5%

STANFORD REI CLINIC

		1985	1986	1987	1988	TOTAL
CYCLES (GIFT)						
	CYCLES STARTED	11	12	10	14	47
						0
	LH SURGE	2	3	1	2	8
	POOR RESPONSE		2	3	2	7
	OTHER		2			2
	SUBTOTAL	2	7	4	4	17
	% ABANDONED	18.2%	58.3%	40.0%	28.6%	36.2%
						0
	HARVESTS, NUMBER	9	5	6	10	30
	NO EGGS	3			2	5
						0
						0
	GIFT	6	5	6	8	25
	NOT PREGNANT	5	4	4	6	19
	PREGNANT	1	1	2	2	6
	BIOCHEMICAL					0
	ABORTION			1	1	2
	ECTOPIC		1			1
	VIABLE	1		1	1	3
ALL	PER CENT OF GIFT'S	16.7%	20.0%	33.3%	25.0%	24.0%
	PER CENT OF HARVESTS	11.1%	20.0%	33.3%	20.0%	20.0%
	PER CENT OF CYCLES	9.1%	8.3%	20.0%	14.3%	12.8%
						0
CLINICAL	PER CENT OF GIFT'S	16.7%	20.0%	33.3%	25.0%	24.0%
	PER CENT OF HARVESTS	11.1%	20.0%	33.3%	20.0%	20.0%
	PER CENT OF CYCLES	9.1%	8.3%	20.0%	14.3%	12.8%
						0
VIABLE	PER CENT OF GIFT'S	16.7%	0.0%	16.7%	12.5%	12.0%
	PER CENT OF HARVESTS	11.1%	0.0%	16.7%	10.0%	10.0%
	PER CENT OF CYCLES	9.1%	0.0%	10.0%	7.1%	6.4%

EMMET J. LAMB, M.D.
STANFORD UNIVERSITY SCHOOL OF MEDICINE
STANFORD, CA 94305
Department of Gynecology and Obstetrics
Section of Reproductive Endocrinology and Infertility
(415) 723-6950 (Academic)
(415) 723-5251 (Patients)

March 1, 1989

Mark Bulkan
Office of Congressman Ron Wyden
House of Representatives
Washington, DC 20515

Dear Mr. Bulkan:

As I anticipated might be the case when I spoke with you recently on the phone, I was not able to get the current data for our IVF program. As a substitute, admittedly a poor one, I enclose the attached tables. These are reports I generated for a visit by Dr. Richard Marrs who consulted with us in 1987 on how to improve our results. I suspect that the current information would be very similar. Our policies and patient mix have not changed in ways that would influence these figures.

Table R-10 and R-11 list the indications for IVF and the number of cycles. About 15% of all cycles were for couples with a male factor, about 15% for idiopathic infertility, and the rest for either endometriosis or tubal disease. Our results were essentially the same for the later two and, thus, we lump them together.

Table R-8 contains 3 tables of 2 X 2 design to show the effects of age on conception. Because of the small sample sizes, none of the differences seen are statistically significant. The notations below each table related to the statistical analysis. To use the first table as an example, the probability of a positive pregnancy test was .17 (17%) for those under age 35, .10 for those over 35. The likelihood of having a positive test was 1.25 times as great for the younger patients (LR+).

Table R-3 shows the pregnancy rates for this group of patients. I am sure you are familiar with the format. Table R-15 shows a similar table for the ideal group with no male problem and no age problem.

I am sorry that I was unable to get you the current data. I expected to have it ready within shouting distance of your deadline. However, I was recently saddled with a new job here which took up all my time.

Sincerely yours,

Emmet J. Lamb, M.D.

STANFORD UNIVERSITY MEDICAL CENTER
STANFORD, CALIFORNIA 94305 • (415) 723-5505

STANFORD UNIVERSITY SCHOOL OF MEDICINE
Department of Gynecology and Obstetrics

STANFORD IN VITRO FERTILIZATION (IVF) TEAM

EMMET J. LAMB, M.D., is the director of Reproductive Endocrinology and Infertility. He trained in obstetrics and gynecology at UCLA and in reproductive endocrinology at UCLA, Stockholm University and Oxford University. He has been on the faculty of the Department of Gynecology and Obstetrics at Stanford for over 20 years.

AMIN MILKI, M.D., trained in obstetrics and gynecology at the American University of Beirut. He completed a fellowship in reproductive endocrinology at Stanford and is a faculty member of the Department of Gynocology and Obstetrics here.

LINDA C. GIUDICE, M.D., has a Ph.D. in biological chemistry from UCLA. She trained in obstetrics and gynecology at Stanford and Washington University in St. Louis. She recently completed a fellowship in reproductive endocrinology and infertility at Stanford and is a faculty member of the Department of Gynecology and Obstetrics here.

TSAI-FENG WU, Ph.D., has been the manager of the Reproductive Endo[illegible] and Infertility Laboratory for the past eight years. She has [illegible] biochemistry from Indiana University.

LISA HO, M.S., is a gamete biologist working in the Reproductive Endocrinology and Infertility Laboratory. She has a master's degree in medical microbiology from Indiana State University.

IMAM EL DANASOURI, DVM., he has a Ph.D. in reproduction and andrology from Ustus-Liebig University, West Germany. Where he has acquired extensive experience in embryo transfer and freezing of semen and embryos for the past eight years.

NANCY CUSTODIO, RN, is the In Vitro Fertilization Nurse Coordinator. She has been a registered nurse for over seven years. Her specialty is in high risk maternal child health. She holds a bachelor's degree from San Jose State University and a nursing degree from De Anza College.

ELLEN CUNEO, RN, is part of the in vitro fertilization team. She has been a registered nurse for fourteen years. She has a bachelor's degree from the University of San Francisco and has worked in specialty procedures for the last twelve years.

JANE ZIMMERMAN, M.S.W., is the social worker for the IVF program. She has a bachelor's degree in philosophy from Barnard College and a master's degree in social work form the University of California at Berkeley.

Appointment Secretary: Pam Allinson, (415) 723-5251

Nurse Coordinator: Nancy Custodio, (415) 723-5251

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IVF/GIFT SURVEY

CLINIC NAME: JOHN MUIR MEDICAL CENTER
ADDRESS: IN VITRO FERTILIZATION PROGRAM
1601 YGNACIO VALLEY RD
WALNUT CREEK CA 94598
ELWOOD L. KRONICK M.D. 415-932 2565
CONTACT PERSON: GLENN ZORN, PH.D
PHONE NUMBER: 415 947 5285

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/1/1986

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ____
   - (b) Community hospital based ✓
   - (c) University based ____
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

[illegible] How many Board Certified Obstetricians/Gynecologists participate in your clinic? 6

6. How many other professionals participate in your clinic?
   - (a) Physicians 10
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 5
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 3
   - (f) Radiology (Ultrasound) Technicians 4
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 3
   - (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF March 1984 GIFT June 1985

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9. How many different patients were stimulated?
1987 IVF 233 1988 IVF 158
GIFT 8 GIFT 4

10. How many stimulation cycles were performed?
1987 IVF 718 1988 IVF 390
GIFT 22 GIFT 14

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 365 1988 300

How many embryo transfer cycles were performed?
1987 310 1988 264

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 15 1988 10

13. What were the number and percentage of patients/ on IRB approved research protocols?
1987 100 % 1988 100 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ 33 % 1988 IVF ___ 37 %
GIFT ___ 0 % GIFT ___ 0 %
(b) Endometriosis:
1987 IVF ___ 17 % 1988 IVF ___ 19 %
GIFT ___ 20 % GIFT ___ 10 %
(c) Male infertility:
1987 IVF ___ 26 % 1988 IVF ___ 21 %
GIFT ___ 47 % GIFT ___ 60 %
(d) Unexplained infertility:
1987 IVF ___ 24 % 1988 IVF ___ 23 %
GIFT ___ 33 % GIFT ___ 30 %
(e) Other (explain): ____________________
1987 IVF ___ ___ % 1988 IVF ___ ___ %
GIFT ___ ___ % GIFT ___ ___ %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ 5 % 1988 IVF ___ 8 %
GIFT ___ 0 % GIFT ___ 0 %
(b) 31-35:
1987 IVF ___ 25 % 1988 IVF ___ 21 %
GIFT ___ 20 % GIFT ___ 0 %
(c) 36-40:
1987 IVF ___ 51 % 1988 IVF ___ 47 %
GIFT ___ 60 % GIFT ___ 50 %

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(d) 41-45:
1987 IVF 10 % 1988 IVF 21 %
GIFT 20 % GIFT 50 %
(e) >45:
1987 IVF 1 % 1988 IVF 1 %
GIFT 0 % GIFT 0 %

16. How many clinical pregnancies were produced?
1987 IVF 81 1988 IVF 61
GIFT 3 GIFT 2

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 64 1988 IVF 16
GIFT 2 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 6 1988 IVF 47
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 2 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 17 %
GIFT 0 %

1988 IVF 21 %
GIFT 0 %

[illegible] What are the qualifications of the director of the embryo laboratory? Ph.D. Embryology 15 yrs experience in tissue Culture 5 yrs experience in IVF

22. Who supervises the laboratory director? MEDICAL Director Laboratory

23. Does the clinic participate in an external laboratory proficiency testing program? YES
If the answer is yes, please specify which program.
JCAH

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? YES

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ________
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

See accompanying letter

JOHN
MUIR
MEDICAL
CENTER

1601 Ygnacio Valley Road • Walnut Creek, California 94598-3194 • (415) 939-3000

December 8, 1988

The Honorable Ron Wyden
Congress of the United States
Suite 1406
Longworth House Office Building
Washington, D.C. 20515

Dear Sir,

Enclosed please find the questionnaire that you requested we complete concerning our In Vitro Fertilization program. We appreciate your efforts to help educate prospective patients and the general public in the areas of assisted reproductive technologies. As you are aware, this field is rapidly changing and it is often difficult for the public to evaluate various IVF protocols and centers. In so doing, you are also performing a much needed service for the physicians and scientists who work in this field.

Our program is a community based hospital located in a suburb near San Francisco. We have had over 160 deliveries and more than fifty ongoing pregnancies as a result of our IVF efforts over the past 5 years. Our physicians are in private practice and we are not associated with any university or resident training program. Consequently, our patients have continuity of care in that the same physician sees and examines the patients daily during the duration of the procedure. Repeat patients benefit from seeing the same physician as before so previously unsuccessful cycles can be analyzed and adjusted in attempts to improve their chances of success. Everyday the team of laboratory scientist and physicians discuss all on going patient cycles, analyze the results of our daily testing, and make adjustments accordingly.

Our program is a member of S.A.R.T. and adheres to all of the guidelines established by the American Fertility Society for IVF programs. All program physicians and scientists are required to attend educational meetings appropriate to their area of expertise and our protocols are continually being updated to offer our patients the best possible care.

One unique aspect of our program concerns our contract with Kaiser Permanente, which obligates us to perform IVF on all of their patients up to age 43. Kaiser was involved in a class action suit which necessitated this coverage.

Your efforts are greatly appreciated and behalf of everyone in our program, let me wish you well. If we can be of further assistance, please do not hesitate to call.

Respectfully,

Elwood Kronick

Elwood Kronick, M.D.
Med. Dir., IVF Program

Glenn A. Zorn, Ph.D
Sci. Dir., IVF Program

FEB 02 '89 09:40 WHITTIER HOSPITAL P.2

IVF/GIFT SURVEY

CLINIC NAME: Whittier Hospital Medical Center
ADDRESS: 15151 Janine Drive
Whittier, CA 90605

CONTACT PERSON: Lynn Ingram R.N., IVF Co-Ordinator
PHONE NUMBER: (213) 945-3561 ext. 339,342,349

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 1988

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 0

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians 2
   - (b) Laboratory Scientists (PhDs) 2, 1 Reproductive Biologist
     1 Geneticist
   - (c) Nurses 1 Co-ordinator
   - (d) Embryo Lab Technicians/Technologists 0
   - (e) Other Lab Technicians/Technologists Clinical Tech. for blood
   - (f) Radiology (Ultrasound) Technicians 1 drawing
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 0
   - (i) Other (specify) 0

7. How many years has your infertility clinic been in operation? 1985

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1988 GIFT 1988

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9. How many different patients were stimulated?
1987 IVF 0 1988 IVF 9
GIFT 0 GIFT 5

10. How many stimulation cycles were performed?
1987 IVF 0 1988 IVF 13
GIFT 0 GIFT 5

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 0 1988 8

How many embryo transfer cycles were performed?
1987 0 1988 7

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 4

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 0 0 % 1988 IVF 7 78 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 2 40 %
(d) Unexplained infertility:
1987 IVF 0 0 % 1988 IVF 2 22 %
GIFT 0 0 % GIFT 3 60 %
(e) Other (explain): Male factor in addition to tubal or unexplained
1987 IVF 0 0 % 1988 IVF 1 11 % counted above in
GIFT 0 0 % GIFT 1 20 % a. - d.

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 0 % 1988 IVF 5 56 %
GIFT 0 0 % GIFT 4 80 %
(b) 31-35:
1987 IVF 0 0 % 1988 IVF 3 33 %
GIFT 0 0 % GIFT 1 20 %
(c) 36-40:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 1 11 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 2
GIFT 0 GIFT 2

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 2

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple [illegible] Pregnancies
1987 IVF 0 0 % ________________
GIFT 0 0 % ________________

1988 IVF ___ ___ % 2 Pregnancies singletons, 1 triplet
GIFT ___ ___ % 2 Pregnancies Both twin

21. What are the qualifications of the director of the embryo laboratory? Ph.D. Physiology(Reproductive Biology), 1966 U. of Pennsylvania, Member AFS and SART

22. Who supervises the laboratory director? Medical Director.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Except Para 2, 1.

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Clinic is not yet eligible to join. Ph.D. Reproductive Biologist has been a member since Nov., 1986

27. Does the clinic train individuals in IVF or GIFT? no
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ____
    (d) Nurses ______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: HOAG FERTILITY SERVICES
ADDRESS: HOAG MEMORIAL HOSPITAL
351 HOSPITAL ROAD, SUITE 316
NEWPORT BEACH, CA. 92663

Lw

CONTACT PERSON: LAWRENCE B. WERLIN, M.D., MEDICAL DIRECTOR
PHONE NUMBER: (714) 760-2395 - Office
(714) 760-2141 - (Private Number, do not publish)

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. **The following data is current through what date?** 12/20/88

2. **Does your clinic perform IVF/GIFT treatments?** YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. **What type of clinic do you operate? (Place X in appropriate space)**
   - **(a) Private** ______
   - **(b) Community hospital based** X
   - **(c) University based** ______
   - **(d) Other (explain)** ______

4. **How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic?** ONE

5. **How many Board Certified Obstetricians/Gynecologists participate in your clinic?** ONE

6. **How many other professionals participate in your clinic?**
   - **(a) Physicians** -
   - **(b) Laboratory Scientists (PhDs)** 1
   - **(c) Nurses** 3 (2 R.N.'S & 1 NURSE PRACTIONER)
   - **(d) Embryo Lab Technicians/Technologists** 1
   - **(e) Other Lab Technicians/Technologists** 3
   - **(f) Radiology (Ultrasound) Technicians** 1 (full time equiv
   - **(g) Psychologists/Counselors** 1
   - **(h) Secretaries** 3
   - **(i) Other (specify)** 1 DEPT. MANAGER

7. **How many years has your infertility clinic been in operation?** 3 YEARS

8. **When were the clinic's first IVF/GIFT stimulation cycles?**
   IVF OCTOBER, 1987 **GIFT** OCTOBER, 1987

9. How many different patients were stimulated?
1987 IVF 11 1988 IVF 29
GIFT 8 GIFT 15

10. How many stimulation cycles were performed?
1987 IVF 12 1988 IVF 52
GIFT 9 GIFT 21

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 4 1988 29

How many embryo transfer cycles were performed?
1987 4 1988 32 (3 transfers of embryos frozen in 1987)

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 4 1988 7

13. What were the number and percentage of patients on IRB approved research protocols?
1987 19 100% 1988 44 100%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 11 57.8% 1988 IVF 30 68.2%
GIFT 8 42.1% GIFT 14 31.8%
(b) Endometriosis:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 1 7.1%
(c) Male infertility:
1987 IVF 0 0% 1988 IVF 5 16.7%
GIFT 0 0% GIFT 0 0%
(d) Unexplained infertility:
1987 IVF 0 0% 1988 IVF 2 6.7%
GIFT 8 100% GIFT 13 92.9%
(e) Other (explain): ____________________
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 0 0%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 1 5.3% 1988 IVF 5 11.4%
GIFT 1 5.3% GIFT 2 4.5%
(b) 31-35:
1987 IVF 6 31.5% 1988 IVF 16 36.4%
GIFT 1 5.3% GIFT 2 4.5%
(c) 36-40:
1987 IVF 3 15.7% 1988 IVF 8 18.1%
GIFT 4 21% GIFT 6 13.6%

(d) 41-45:
1987 IVF 1 5.3% 1988 IVF 2 4.5 %
GIFT 2 10.6 % GIFT 2 4.5 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 1 2.3%
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 2 of 4 1988 IVF 9 of 29 33%
GIFT 0 of 4 GIFT 3 of 7 42.8% 35% overall

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 3
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 6
GIFT 0 GIFT 3

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% Program began in Oct., 1987
GIFT ___ ___% ___

1988 IVF 1 1/3 Twins
GIFT 0 0 % No births to date

21. What are the qualifications of the director of the embryo laboratory? Ph.D. Reproductive Physiology John Hopkins Univ.
4 years member of embrology lab-Jones Institute, Norfolk, Va.
Director of Andrology ,Director of Cryo Laboratory,Jones Institute

22. Who supervises the laboratory director? Norfolk,Va.
Department Manager & Medical Director

23. Does the clinic participate in an external laboratory proficiency testing program? Yes, RIA Lab participates in Cap Survey
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** Application pending

27. **Does the clinic train individuals in IVF or GIFT?** NO
If the answer is yes, how many individuals in the following specialties have been trained?
   (a) **Physicians** -
   (b) **Laboratory scientists (PhDs)** -
   (c) **Embryo laboratory technicians/technologists** -
   (d) **Nurses** -
   (e) **Other (explain)** -

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

Hoag Fertility Services Center is a Department of Hoag Memorial Hospital located in Newport Beach, Ca.

Our treatment policy is to offer patients individualized protocols specific to their situation. We are a full service center offering a complete spectrum of therapies included:

1.) Ultrasound timing of ovulation

2.) Washed intrauterine insemination

3.) Microsurgery

4.) Full laboratory service including RIA & Andrology

5.) Assisted Reproductive Technologies (ART)

6.) Cryopreservation

7.) Psychological Counseling

With respect to our assisted reproductive technology program, we offer IVF-ET, GIFT, ZIFT and Cryopreservation. Our staff has a number of years of experience at some of the first A.R.T. centers created in the U.S. Consequently our program is able to offer both ultrasound and laparoscopic oocyte retrieval The laboratory and adjacent operating room are used exclusively for our A.R.T. procedures.

We are very proud of our succes to date. All of our patients (100%) undergoing the egg retreival procedure have had a subsequent transfer (mature eggs & sperm for GIFT or pre-embryos for IVF).

Our overall clincial pregnancy rate per retreival procedure is 30% for fresh transfers (non-frozen). Including patients who have had a second transfer of frozen-thawed pre-embryos, the clinical pregnancy rate per retrieval is now 34% and climbing as more patients return for thaw procedures.

Our cryopreservation program has been extremely successful. We will only transfer up to four oocytes or pre-embryos at a time. However, patients may choose to cryopreserve any pre-embryos created beyond four. To date, 50% of our patients undergoing retrieval have excess pre-embryos to freeze with an average of 3.6 pre-embryos frozen per patient. As of December, 1988, 63% of our thawed pre-embryos have survived and subsequently undergone a cleavage division. Although we have only offered cryo for a little over a year, we already have one live birth and one ongoing clinical pregnancy from our first three thaw-transfer procedures.

A second exciting development is our new stimulation regimen. In October, 1988, we initiated the use of GnRH agonist for all patients. With our specific protocol, 45% of the 20 patients stimulated to date achieved a clinical pregnancy. (95% of the patients went toi retrieval (19/20) and nine have continuing clinical pregnanccies with all singleton pregnancies.

We are justifiably very proud of our team and although we cannot guarantee our patients success, we can assure them of our very best effort for each and every one.

IVF/GIFT SURVEY

CLINIC NAME: Infertility, Gynecology & Obstetrics PC.
ADDRESS: 601 E. Hampden #185
Englewood Co 80110
DIRECTOR: William Schoolcraft MD

CONTACT PERSON: Kathy Webb RN
PHONE NUMBER: (303) 788 6271 788 6275

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 0

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3 / 1 that does all IVF & GIFT

6. How many other professionals participate in your clinic?
   - (a) Physicians 3 total 1 does all IVF & GIFT
   - (b) Laboratory Scientists (PhDs) ________
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists ________
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors ________
   - (h) Secretaries 1
   - (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 1½

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 2/88 GIFT 7/87

9. How many different patients were stimulated?
1987 IVF 0 1988 IVF 45
GIFT 18 GIFT 54

10. How many stimulation cycles were performed?
1987 IVF 0 1988 IVF 54
GIFT 20 GIFT 55

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 NA 1988 30

How many embryo transfer cycles were performed?
1987 NA 1988 40

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 18 1988 52

13. What were the number and percentage of patients on IRB approved research protocols?
1987 — —% 1988 — —%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 0 __% 1988 IVF 24 53%
GIFT 0 __% GIFT 0 __%
(b) Endometriosis:
1987 IVF 0 __% 1988 IVF 2 5%
GIFT 12 67% GIFT 32 59%
(c) Male infertility:
1987 IVF 0 __% 1988 IVF 6 13%
GIFT 1 5% GIFT 6 11%
(d) Unexplained infertility:
1987 IVF 0 __% 1988 IVF 3 7%
GIFT 2 11% GIFT 13 24%
(e) Other (explain): Pelvic Adhesions 7/1 pt c premature ovarian failure
1987 IVF 0 __% 1988 IVF 10 22%
GIFT 3 17% GIFT 10 18%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 __% 1988 IVF 42 47%
GIFT 10 55% GIFT 18 34%
(b) 31-35:
1987 IVF 0 __% 1988 IVF 27 60%
GIFT 9 50% GIFT 31 55%
(c) 36-40:
1987 IVF 0 __% 1988 IVF 6 13%
GIFT 3 17% GIFT 12 21%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF NA 1988 IVF 16
GIFT 6 GIFT 26

17. How many women delivered live infants from IVF/GIFT?
1987 IVF NA 1988 IVF –
GIFT 6 GIFT 12

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF [illegible] 1988 IVF 14
GIFT 0 GIFT 13

19. How many ectopic pregnancies resulted?
1987 IVF NA 1988 IVF 2
GIFT 1 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF NA ___% ______________
GIFT 2 33% twins

1988 IVF ___ ___% ______________
GIFT 7 58% twins

21. What are the qualifications of the director of the embryo laboratory? BS + more [illegible] PhD [illegible] currently [illegible] training in [illegible]

22. Who supervises the laboratory director? [illegible] Plus [illegible] Director of Pathology.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** applied for membership

27. **Does the clinic train individuals in IVF or GIFT?** NO
If the answer is yes, how many individuals in the following specialties have been trained?
    - **(a) Physicians** ______
    - **(b) Laboratory scientists (PhDs)** ______
    - **(c) Embryo laboratory technicians/technologists** ______
    - **(d) Nurses** ______
    - **(e) Other (explain)** ______

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

Our practice provides service to the entire Rocky Moutain area. Our program is modeled after the UCLA program, piloted by Dr. David Meldrum, where Dr. Schoolcraft had extensive training. Using Lupron and Pergonal we have excellent follicular recruitment and a low cancelled cycle rate. We attribute our high sucess rate, 35-40%, to this stimulation protocol and to the excellent IVF lab. All equipment and medium used with human embryos is pretested on mouse embryos. In addition, because we are a private practice working out of a private institution only a small core group is involved in both the clinical care and in the laboratory. This provides consistant, highly competent care.

IVF/GIFT SURVEY

CLINIC NAME: Reproductive Genetics, In vitro PC
ADDRESS: 455 S Hudson St Level 3
Denver, COLORADO 80222

CONTACT PERSON: Susan [illegible] [illegible]
PHONE NUMBER: (303) [illegible]-1464

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    - (a) Private X
    - (b) Community hospital based ____
    - (c) University based ____
    - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
    - (a) Physicians 4
    - (b) Laboratory Scientists (PhDs) 1
    - (c) Nurses 2
    - (d) Embryo Lab Technicians/Technologists 2
    - (e) Other Lab Technicians/Technologists ____
    - (f) Radiology (Ultrasound) Technicians 2
    - (g) Psychologists/Counselors ____
    - (h) Secretaries ____
    - (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? 6 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 9/24/82 GIFT ____

9. How many different patients were stimulated?
1987 IVF 121 1988 IVF 161
GIFT 0 GIFT 0

10. How many stimulation cycles were performed?
1987 IVF 173 1988 IVF 254
GIFT 0 GIFT 0

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 130 1988 200

How many embryo transfer cycles were performed?
1987 130 1988 170

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0% 1988 ___ 0%

14. What were the number and percentage of patients/cycles treated for:

This data represents cycles with multifactoral problems

(a) Tubal factor:
1987 IVF 110 69% 1988 IVF 134 71%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 7 4% 1988 IVF 12 6%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF 34 21% 1988 IVF 32 17%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF 9 6% 1988 IVF 11 6%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ___
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients/cycles in the following age groups:
(a) <31:
1987 IVF 14 11.5% 1988 IVF 25 16%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF 52 43% 1988 IVF 69 43%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF 44 36% 1988 IVF 62 38.5%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF 11 9 % 1988 IVF 5 3 %
GIFT __ __ % GIFT __ __ %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT __ __ % GIFT __ __ %

16. How many clinical pregnancies were produced?
1987 IVF 24 1988 IVF 36
GIFT __ GIFT __

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 13 1988 IVF 10
GIFT __ GIFT __

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 14
GIFT __ GIFT __

Undelivered: 2 sets of twins and 1 set of quintuplets

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT __ GIFT __

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 14 11 % one set of twins
GIFT __ __ %
1988 IVF 24 14 % 3 sets of twins + one set of triplets delivered
GIFT __ __ %

% is based on births / embryo transfer

21. What are the qualifications of the director of the embryo laboratory? 20 years of experience in Mammalian IVF
Professor - University of Colorado. Research

22. Who supervises the laboratory director? Not necessary

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ______
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ______
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Reproductive Endocrinology and Fertility
ADDRESS: University of Connecticut School of Medicine
Department of Obstetrics and Gynecology
263 Farmington Avenue
Farmington, Connecticut 06032
CONTACT PERSON: Anthony A. Luciano, M.D.
PHONE NUMBER: (203) 679-2193 - business/research
(203) 679-4580 - clinic

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/1/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    - (a) Private ______
    - (b) Community hospital based ______
    - (c) University based X
    - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 4

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
    - (a) Physicians 2 Fellows and 1 resident
    - (b) Laboratory Scientists (PhDs) 1
    - (c) Nurses 3
    - (d) Embryo Lab Technicians/Technologists 3
    - (e) Other Lab Technicians/Technologists 5
    - (f) Radiology (Ultrasound) Technicians 0
    - (g) Psychologists/Counselors 1
    - (h) Secreteries 3
    - (i) Other (specify) Financial Assistant

7. How many years has your infertility clinic been in operation? > 10 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1985

9. How many different patients were stimulated?
1987 IVF 30 1988 IVF 41
GIFT 8 GIFT 7

10. How many stimulation cycles were performed?
1987 IVF 67 1988 IVF 89
GIFT 8 GIFT 7

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 34 1988 47

How many embryo transfer cycles were performed?
1987 32 1988 34

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 8 1988 7

13. What were the number and percentage of patients on IRB approved research protocols?
1987 all 100% 1988 all 100%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 12 40% 1988 IVF 18 38%
GIFT 0 % GIFT 0 %
(b) Endometriosis:
1987 IVF 11 37 % 1988 IVF 15 31%
GIFT 3 38% GIFT 3 43%
(c) Male infertility:
1987 IVF 3 10 % 1988 IVF 7 14.5%
GIFT 3 38 % GIFT 1 14 %
(d) Unexplained infertility:
1987 IVF 3 10% 1988 IVF 7 14.5%
GIFT 2 24% GIFT 3 43 %
(e) Other (explain):
1987 IVF 1 3 % 1988 IVF 1 2 %
GIFT 0 % GIFT 0 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 2 6 % 1988 IVF 5 12%
GIFT 2 25 % GIFT 0 %
(b) 31-35:
1987 IVF 16 53% 1988 IVF 21 51%
GIFT 5 63% GIFT 4 57 %
(c) 36-40:
1987 IVF 8 27 % 1988 IVF 15 37%
GIFT 1 12 % GIFT 3 4%

(d) 41-45:
1987 IVF 2 7 % 1988 IVF 0 %
GIFT 0 % GIFT 0 %

(e) >45:
1987 IVF 2 7 % 1988 IVF 0 %
GIFT 0 % GIFT 0 %

16. How many clinical pregnancies were produced?
1987 IVF 4 1988 IVF 4
GIFT 1 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 2 1988 IVF 3
GIFT 1 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 1988 IVF 3
GIFT GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 67 % 2 sets quadruplets
GIFT %

1988 IVF % no multiple births delivered yet
GIFT %

21. What are the qualifications of the director of the embryo laboratory? John Peluso, Ph.D.
15 years experience with eggs and embryos

22. Who supervises the laboratory director? Anthony A. Luciano, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 5
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 5
    (d) Nurses 3
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Our patient population constitutes infertile married couples from the middle/upper middle class society of Northern New England. The majority of them have exhausted the traditional therapies within our service or from other fertility clinics.

IVF/GIFT SURVEY

CLINIC NAME: REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY DIVISION
ADDRESS: MOUNT SINAI HOSPITAL
675 TOWER AVE.
HARTFORD, CT. 06112

CONTACT PERSON: AUGUSTO P. CHONG, M.D.
PHONE NUMBER: (203) 242-6201

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 10-30-88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic?. 0

6. How many other professionals participate in your clinic?
   - (a) Physicians ______
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 3
   - (e) Other Lab Technicians/Technologists ______
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors ______
   - (h) Secretaries 2
   - (i) Other (specify) — IVF-ET/GIFT COORDINATOR

7. How many years has your infertility clinic been in operation? APPROX. 4 YEARS

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF APRIL 1984 GIFT FEBRUARY 1987

9. How many different patients were stimulated?
1987 IVF 45 1988 IVF 47
GIFT 5 GIFT 7

10. How many stimulation cycles were performed?
1987 IVF 45 1988 IVF 47
GIFT 5 GIFT 7

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 26 1988 39

How many embryo transfer cycles were performed?
1987 22 1988 25

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 4 1988 5

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 8 18% 1988 IVF 9 19%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 3 6% 1988 IVF 4 9%
GIFT 2 0% GIFT 3 60%
(c) Male infertility:
1987 IVF 20 44% 1988 IVF 18 38%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF 5 12% 1988 IVF 10 21%
GIFT 2 50% GIFT 2 40%
(e) Other (explain): PELVIC ADHESIONS, OVULATORY DYSFUCTION
1987 IVF 9 20% 1988 IVF 6 13%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 8 18% 1988 IVF 7 15%
GIFT 1 25% GIFT 0 ___%
(b) 31-35:
1987 IVF 20 44% 1988 IVF 27 57%
GIFT 2 50% GIFT 2 40%
(c) 36-40:
1987 IVF 15 33% 1988 IVF 11 24%
GIFT 1 25% GIFT 3 60%

(d) 41-45:
1987 IVF 2 5% 1988 IVF 2 4%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF 0 0% 1988 IVF 0 ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 3 1988 IVF 4
GIFT 1 GIFT 5

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 2 1988 IVF 1
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 2 (OVER 26 WEEKS)
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ___
GIFT ___ ___% ___

1988 IVF 1 14% TWINS
GIFT ___ ___% ___

21. What are the qualifications of the director of the embryo laboratory? MEDICAL TECHNOLOGIST & (REPRODUCTIVE ENDOCRINOLOGIST)

22. Who supervises the laboratory director? THE DIRECTOR OF THE IVF-ET/GIFT PROGRAM

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? YES

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
   (a) Physicians ____
   (b) Laboratory scientists (PhDs) 1
   (c) Embryo laboratory technicians/technologists 2
   (d) Nurses 1
   (e) Other (explain) ____

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

- Only 18.5% of our patients undergoing ivf had tubal factor as the reason for their infertility
- The male was the reason for the infertility in 41% of our patient population for ivf
- One third (33%) of our patients who entered the IVF program were older than 36 years of age
- The recent addition of embryo cryopreservation techniques should increase our pregnancy rates by about 3-5%.

IVF/GIFT SURVEY

CLINIC NAME: Yale School of Medicine
ADDRESS: 333 Cedar Street, P.O. Box 3333
New Haven, CT 06510

CONTACT PERSON: Alan H. DeCherney, M.D.
PHONE NUMBER: (203) 785-4019

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/1/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ________
   - (b) Community hospital based ________
   - (c) University based X
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 5

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 5

6. How many other professionals participate in your clinic?
   - (a) Physicians 2
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 3
   - (d) Embryo Lab Technicians/Technologists 4
   - (e) Other Lab Technicians/Technologists 0
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 2
   - (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 6

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 4/82 GIFT 6/85

9. How many different patients were stimulated?
1987 IVF 279 1988 IVF 293
GIFT 33 GIFT 17

10. How many stimulation cycles were performed?
1987 IVF 473 1988 IVF 466
GIFT 40 GIFT 22

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 381 1988 342

How many embryo transfer cycles were performed?
1987 326 1988 286

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 26 1988 13

13. What were the number and percentage of patients on IRB approved research protocols?
1987 2 0 % 1988 2 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 166 60 % 1988 IVF 162 55 %
GIFT 1 3 % GIFT 2 12 %
(b) Endometriosis:
1987 IVF 32 11 % 1988 IVF 25 9 %
GIFT 1 3 % GIFT 3 18 %
(c) Male infertility:
1987 IVF 38 14 % 1988 IVF 46 16 %
GIFT 12 36 % GIFT 4 24 %
(d) Unexplained infertility:
1987 IVF 32 11 % 1988 IVF 46 16 %
GIFT 18 55 % GIFT 13 76 %
(e) Other (explain): ____________
1987 IVF 11 4 % 1988 IVF 10 3 %
GIFT 1 3 % GIFT 0 0 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 56 20 % 1988 IVF 52 18 %
GIFT 3 9 % GIFT 5 29 %
(b) 31-35:
1987 IVF 98 35 % 1988 IVF 117 40 %
GIFT 17 51 % GIFT 6 35 %
(c) 36-40:
1987 IVF 94 34 % 1988 IVF 83 28 %
GIFT 10 30 % GIFT 9 53 %

(d) 41-45:
1987 IVF 27 10 % 1988 IVF 37 13 %
GIFT 1 9 % GIFT 2 12 %
(e) >45:
1987 IVF 4 1 % 1988 IVF 4 1 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 63 1988 IVF 51
GIFT 2 GIFT 2

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 32 1988 IVF 23
GIFT 1 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 14
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 8 10 % 4 sets twins
GIFT 0 0 % -

1988 IVF 0 0 % -
GIFT 0 0 % No multiple pregnancy (freezing)

21. What are the qualifications of the director of the embryo laboratory? Board eligible Reproductive Endocrinology

22. Who supervises the laboratory director? Director of Reproductive Endocrine Division

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 6
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 3
    (d) Nurses 3
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Our pregnancy rate for patients with tubal disease only, less than 35 years of age is 14%/cycle and 51% cumulative pregnancy rate

IVF/GIFT SURVEY

CLINIC NAME: Reproductive Endocrine and Fertility Center.
ADDRESS: 4745 Ogletown - Stanton Rd
Medical Center of Delaware
Newark, Delaware 19718

CONTACT PERSON: JOY BIANCOSINO RN, NURSE coordinator
PHONE NUMBER: 302-733 4600

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Feb 14, 1989.

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ____
   - (b) Community hospital based ✓
   - (c) University based ____
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? ONE

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? same ONE as above

6. How many other professionals participate in your clinic?
   - (a) Physicians ____
   - (b) Laboratory ~~Scientists~~ (PhDs) ONE
   - (c) Nurses two
   - (d) Embryo Lab Technicians/Technologists ONE
   - (e) Other Lab Technicians/Technologists ____
   - (f) Radiology (Ultrasound) Technicians ____
   - (g) Psychologists/Counselors 2
   - (h) Secretaries 2
   - (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? NINE MONTHS

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF March 1988 GIFT April 1988

NEW clinic 1988 / March-April.

9. How many different patients were stimulated?
1987 IVF ____ 1988 IVF 50 1988 9
GIFT ____ GIFT 6 Combined

10. How many stimulation cycles were performed?
1987 IVF ____ 1988 IVF 118 combined 9
GIFT ____ GIFT 10

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ____ d 1988 70

How many embryo transfer cycles were performed?
1987 ____ 1988 64

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ____ 1988 6

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ____ ____% 1988 ____ 0%

14. What were the number and percentage of patients treated for:

Combined

(a) Tubal factor:
1987 IVF ____ ____% 1988 IVF 44 73%
GIFT ____ ____% GIFT 0 0% 1 11.1%

(b) Endometriosis:
1987 IVF ____ ____% 1988 IVF 4 6.7%
GIFT ____ ____% GIFT 1 16.6% 2 22.2%

(c) Male infertility:
1987 IVF ____ ____% 1988 IVF 8 13.5% 1 11.1%
GIFT ____ ____% GIFT 2 33.3%

(d) Unexplained infertility:
1987 IVF ____ ____% 1988 IVF 1 1.6%
GIFT ____ ____% GIFT 3 50% 3 33.3%

(e) Other (explain): Donor Egg
1987 IVF ____ ____% 1988 IVF 2 3.3%
GIFT ____ ____% GIFT 0 0% 1 11.1%
Annovulation

15. What were the number and percentage of patients in the following age groups:

(a) <31:
1987 IVF ____ ____% 1988 IVF 21 (31.6)
GIFT ____ ____% GIFT 2 (33)%

(b) 31-35:
1987 IVF ____ ____% 1988 IVF 22 (33)
GIFT ____ ____% GIFT 5 (75)%

(c) 36-40:
1987 IVF ____ ____% 1988 IVF 13 (19.6%)
GIFT ____ ____% GIFT 1 (15)

(d) 41-45:
1987 IVF ___ ___% 1988 IVF (2) 3 %
GIFT ___ ___% GIFT (0) 0 %

(e) >45:
1987 IVF ___ ___% 1988 IVF (0) 0 %
GIFT ___ ___% GIFT (0) – %

16. How many clinical pregnancies were produced?
1987 IVF ___ 1988 IVF 9
GIFT ___ GIFT 2 Combined 5

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF 0
GIFT ___ GIFT 0 only in Business For 9 months

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 4
GIFT ___ GIFT 2 comb 3

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF 0
GIFT ___ GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ______________________
GIFT ___ ___% ______________________

1988 IVF ___ ___% ______________________
GIFT ___ ___% ______________________

21. What are the qualifications of the director of the embryo laboratory? PHD · Reproductive physiology

22. Who supervises the laboratory director? Reproductive Endocrinologist with

23. Does the clinic participate in an external laboratory proficiency testing program? ___________
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? applying.

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ______
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists ____
    (d) Nurses ______
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: COLUMBIA HOSPITAL FOR WOMEN
ADDRESS: 2440 M. ST. N.W. SUITE 401
WASHINGTON DC
20037

CONTACT PERSON: MAURICE J. BUTLER MD
PHONE NUMBER: (202) 293-5249

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12-88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ____
   - (b) Community hospital based X
   - (c) University based ____
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? —

6. How many other professionals participate in your clinic?
   - (a) Physicians 2
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 3
   - (d) Embryo Lab Technicians/Technologists 3
   - (e) Other Lab Technicians/Technologists ____
   - (f) Radiology (Ultrasound) Technicians —
   - (g) Psychologists/Counselors 1
   - (h) Secretaries ____
   - (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? 15

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1987 GIFT 1987

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF 94
GIFT ______ GIFT 6

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF 162
GIFT ______ GIFT 6

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ________ 1988 134

How many embryo transfer cycles were performed?
1987 ________ 1988 117

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ________ 1988 6

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ 0%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF 48 51%
GIFT ___ ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 26 27%
GIFT ___ ___% GIFT 3 50%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 15 16%
GIFT ___ ___% GIFT 0 0%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF 5 6%
GIFT ___ ___% GIFT 3 50%
(e) Other (explain): ________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF 2 2%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF 30 31%
GIFT ___ ___% GIFT 2 33%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF 55 58%
GIFT ___ ___% GIFT 4 66%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF 7 7%
GIFT ___ ___% GIFT 0 0%
(e) >45:
1987 IVF ___ ___% 1988 IVF 0 0%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF ____ 1988 IVF 27
GIFT ____ GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ____ 1988 IVF 4
GIFT ____ GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ____ 1988 IVF 15
GIFT ____ GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF ____ 1988 IVF 3
GIFT ____ GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ~~2~~ ~~50~~% ~~2 SETS OF TWINS~~
GIFT ~~0~~ ___%

1988 IVF 2 50% 2 SETS OF TWINS
GIFT 0 ___%

21. What are the qualifications of the director of the embryo laboratory? PhD IN GENETICS

22. Who supervises the laboratory director? __________

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? YES

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? YES

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 1
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 2
    (d) Nurses 2
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: George Washington University IVF Program
ADDRESS: 2150 Pennsylvania Ave., N.W.
Washington, D.C. 20037

CONTACT PERSON: Robert J. Stillman, M.D. and Paul R. Gindoff, M.D.
PHONE NUMBER: (202) 994-4614 or 994-5060

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   - (a) Physicians 1
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists ______
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 2
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 1983

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1986

9. How many different patients were stimulated?
1987 IVF 12 1988 IVF 57
GIFT 10 GIFT 14

10. How many stimulation cycles were performed?
1987 IVF 12 1988 IVF 61
GIFT 10 GIFT 14

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 11 1988 50

How many embryo transfer cycles were performed?
1987 7 1988 44

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 10 1988 14

13. What were the number and percentage of patients on IRB approved research protocols?
1987 22 100% 1988 71 100%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 8 37% 1988 IVF 29 41%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 4 18% 1988 IVF 13 18%
GIFT 1 4% GIFT 2 3%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 15 21%
GIFT 6 27% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 3 14% GIFT 12 17%
(e) Other (explain): ___
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 1 10% GIFT 0 ___%
(b) 31-35:
1987 IVF 6 50% 1988 IVF 20 35%
GIFT 5 50% GIFT 8 57%
(c) 36-40:
1987 IVF 3 25% 1988 IVF 30 52%
GIFT 4 40% GIFT 6 43%

(d) 41-45:
1987 IVF 3 25 % 1988 IVF 7 12 %
GIFT ___ ___ % GIFT ___ ___ %

(e) >45:
1987 IVF 0 ___ % 1988 IVF 0 ___ %
GIFT 0 ___ % GIFT 0 ___ %

16. How many clinical pregnancies were produced?
1987 IVF 2 1988 IVF 12
GIFT 3 GIFT 5

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 1 1988 IVF 1
GIFT 2 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 9
GIFT 0 GIFT 5

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 1 GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 50 % Twins
GIFT ___ ___ % ___

1988 IVF 1 10 % Twins
GIFT ___ ___ % ___

21. What are the qualifications of the director of the embryo laboratory? Ph.D., ten years of IVF experience, experienced andrologist

22. Who supervises the laboratory director? Robert J. Stillman, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 3
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists 1
    (d) Nurses 4
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

1. Academic institution. Subspecialty trained physicians and team.

2. GIFT - 33% clinical pregnancy per gamete transfer.

3. IVF/ER - 27.4% clinical pregnancy per embryo transfer

   23% clinical pregnancy per cycle

4. Cryopreservation of embryos, Host Uterus Program and egg recovery for GIFT or IVF at the time of diagnostic laparoscopy available.

5. Transvaginal oocyte recovery for in vitro fertilization.

6. Comprehensive subspecialty infertility care including full range of assisted reproductive technologies.

IVF/GIFT SURVEY

CLINIC NAME: The Fertility Institute of Boca Raton
ADDRESS: West Boca Medical Center
21644 State Rd 7, Highway 441
Boca Raton, Florida. 33428.

CONTACT PERSON: Joseph E. Schahli
PHONE NUMBER: 407-488-8000

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12-01-88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ____
   - (b) Community hospital based X
   - (c) University based ____
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 0

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 0
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 3
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 0
   - (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? 1

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 11-06-87 GIFT 03-04-88

9. How many different patients were stimulated?
1987 IVF 2 1988 IVF 20
GIFT 0 GIFT 9

10. How many stimulation cycles were performed?
1987 IVF 4 1988 IVF 35
GIFT 0 GIFT 10

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 2 1988 31

How many embryo transfer cycles were performed?
1987 2 1988 26

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 9

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0% 1988 0 0%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 2 100% 1988 IVF 13 57%
GIFT — —% GIFT 0 0%
(b) Endometriosis:
1987 IVF 0 —% 1988 IVF 1 4%
GIFT 0 —% GIFT 1 11%
(c) Male infertility:
1987 IVF 0 —% 1988 IVF 6 27%
GIFT 0 —% GIFT 5 56%
(d) Unexplained infertility:
1987 IVF 0 —% 1988 IVF 2 10%
GIFT 0 —% GIFT 3 33%
(e) Other (explain): ___________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 1 50% 1988 IVF 1 5%
GIFT — —% GIFT ___ ___%
(b) 31-35:
1987 IVF 1 50% 1988 IVF 10 50%
GIFT — —% GIFT 5 56%
(c) 36-40:
1987 IVF 0 0% 1988 IVF 5 25%
GIFT — —% GIFT ___ ___%

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 1 5 %
GIFT ____ ____ % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 1 5 %
GIFT ____ ____ % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 4
GIFT 0 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 1 (Girl)
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 3
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ____ ____ % ____________
GIFT ____ ____ % ____________

1988 IVF 1 100 % Singleton.
GIFT 0 0 % ____________

21. What are the qualifications of the director of the embryo laboratory? 7 yrs human Embryo laboratory Experience; Established 4 successful IVF Programs Throughout country

22. Who supervises the laboratory director? No one

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? ?

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ________
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

#14- Some patients had multiple Etiologies

#16- IN Addition to Clinical Pregnancies there were 2 Biochemical Preg 1 IVF & 1 GIFT

#10 "Attempted Cycle" = Pt on cycle day 3 presentation, for medication. A few were cancelled because did not meet our criteria

IVF/GIFT SURVEY

CLINIC NAME: PARK AVENUE WOMEN'S CENTER

ADDRESS: UNIVERSITY OF FLORIDA ASSOCIATES (SHANDS HOSPITAL)

817 NW 56 TERRACE
SUITE C
GAINESVILLE, FL 32605

(OR) DIV. OF REPRODUCTIVE ENDOCRINOLOGY + INFERTILITY
JHMHC - J294
GAINESVILLE, FL 32610

CONTACT PERSON: R. STAN WILLIAMS M.D. / LYNN O'DRISCOLL, RN

PHONE NUMBER: 392-6200

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 0

6. How many other professionals participate in your clinic?
   - (a) Physicians ______
   - (b) Laboratory Scientists (PhDs) ______
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists ______
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors ______
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 6 mos.

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 8/88 GIFT 9/88

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF 6
GIFT _____ GIFT 1

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF 7
GIFT _____ GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ________ 1988 ________

How many embryo transfer cycles were performed?
1987 ________ 1988 6

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ________ 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 5 83%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF 4 66%
GIFT ___ ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 2 33%
GIFT ___ ___% GIFT 0 ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 0 0%
GIFT ___ ___% GIFT 1 100%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF 0 ___%
GIFT ___ ___% GIFT 0 ___%
(e) Other (explain): ____________________
1987 IVF ___ ___% 1983 IVF 0 ___%
GIFT ___ ___% GIFT 0 ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF 1 33%
GIFT ___ ___% GIFT 0 0%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF 1 16%
GIFT ___ ___% GIFT 1 100%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF 3 50%
GIFT ___ ___% GIFT 0 0%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF 0 ___%
GIFT ___ ___% GIFT 0 ___%
(e) >45:
1987 IVF ___ ___% 1988 IVF 0 ___%
GIFT ___ ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF ___ 1988 IVF 3
GIFT ___ GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF 0
GIFT ___ GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 1
GIFT ___ GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF 1
GIFT ___ GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ___
GIFT ___ ___% ___

1988 IVF ___ ___% ___
GIFT ___ ___% ___

21. What are the qualifications of the director of the embryo laboratory? B.S. Medical Technology

22. Who supervises the laboratory director? IVF Medical Director

23. Does the clinic participate in an external laboratory proficiency testing program? no
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? no - not qualified

27. Does the clinic train individuals in IVF or GIFT? no
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians _______
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

There was a previous IVF program at University of Florida 1986-1988. In July 1988 the previous medical director left and the program was changed to the current protocols. Only data on the ongoing IVF program is listed.

IVF/GIFT SURVEY

CLINIC NAME: The Fertility Institute of Northwest Florida,Inc.
ADDRESS: Gulf Breeze Hospital Suite 202
Gulf Breeze, Florida 32561

CONTACT PERSON: Janice Pyle RN
PHONE NUMBER: (904) 934-3900

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 13Nov88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ____
   - (b) Community hospital based x
   - (c) University based ____
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? one
Richard P. Dickey, MD, PhD

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? one

6. How many other professionals participate in your clinic?
   - (a) Physicians one (MD)
   - (b) Laboratory Scientists (PhDs) one (MD)
   - (c) Nurses two
   - (d) Embryo Lab Technicians/Technologists two
   - (e) Other Lab Technicians/Technologists two
   - (f) Radiology (Ultrasound) Technicians one
   - (g) Psychologists/Counselors one
   - (h) Secretaries three
   - (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? 1.4

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF August 1987 GIFT August 1987

9. How many different patients were stimulated?
1987 IVF 16 1988 IVF 36
GIFT 15 GIFT 32

10. How many stimulation cycles were performed?
1987 IVF 14 1988 IVF 36
GIFT 15 GIFT 37

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 12 1988 31 ~~36~~

How many embryo transfer cycles were performed?
1987 12 1988 29

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 10 1988 27

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0 % 1988 ___ 0 %

14. What were the number and percentage of patients treated for:

(f)Multiple factors:
1987 I 5 45%
G 1 10%

1988 I 8 29%
G 8 32%

(a) Tubal factor:
1987 IVF 8 73% 1988 IVF 27 96%
GIFT 1 10 % GIFT 2 10 %

(b) Endometriosis:
1987 IVF 2 18% 1988 IVF 0 0 %
GIFT 5 50 % GIFT 11 44 %

(c) Male infertility:
1987 IVF 1 9 % 1988 IVF 3 11 %
GIFT 3 12 % GIFT 3 12 %

(d) Unexplained infertility:
1987 IVF 0 0 % 1988 IVF 1 4 %
GIFT 2 20 % GIFT 7 28 %

(e) Other (explain): PCO, Sperm antibodies, cervical, congenital
1987 IVF 1 10% 1988 IVF 4 14%
GIFT 2 20 % GIFT 3 12 %

15. What were the number and percentage of patients in the following age groups:

(a) <31:
1987 IVF 3 27 % 1988 IVF 9 32 %
GIFT 2 20 % GIFT 7 28 %

(b) 31-35:
1987 IVF 9 82 % 1988 IVF 14 50 %
GIFT 6 60 % GIFT 13 52 %

(c) 36-40:
1987 IVF 1 9 % 1988 IVF 5 18 %
GIFT 2 20 % GIFT 4 16 %

(d) 41-45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 1 4%

(e) >45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF 3 1988 IVF 4
GIFT 2 GIFT 10

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 2
GIFT 0 GIFT 3

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 4
GIFT 0 GIFT 5

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___% ___
GIFT 0 ___% ___

1988 IVF 0 ___% ___
GIFT 1 20% twins

21. What are the qualifications of the director of the embryo laboratory? MD (China, OBG) Laboratory Fellow/Research associate at M.D. Anderson Hosp, Houston; Louisiana State Univ. Med Ctr. New Orleans; The Fertility Institute of New Orleans, Richard P. Dickey MD, PhD

22. Who supervises the laboratory director? T. Olar PhD. The Fertility Institute of New Orleans

23. Does the clinic participate in an external laboratory proficiency testing program? on as needed basis
If the answer is yes, please specify which program.
The Fertility Institute of New Orleans

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? applied for (Dr. Dickey has info)

27. Does the clinic train individuals in IVF or GIFT? in-house only
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists two
    (d) Nurses three
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

This clinic is the only viable and successful program available to patients in northwest Florida and south Alabama. Our direct affiliation with The Fertility Institute of New Orleans insures constant update and supervision of all materials and methods. All patient treatment protocols follow those provided by the parent institution. We provide comprehensive management of fertility couples. Our sperm bank is strictly governed by the guidelines set forth by the American Fertility Society.

IVF/GIFT SURVEY

CLINIC NAME: IVF/ET program at Memorial Medical Center of Jacksonville
ADDRESS: 3343 University Boulevard South
Jacksonville / , Florida 32216

CONTACT PERSON: MARWAN M. SHAYKH M.D.
PHONE NUMBER: 904-3911143 , 904-2726242

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? August/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? One

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? None

6. How many other professionals participate in your clinic?
   - (a) Physicians 4
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists ______
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 2
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? Jan. 86

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 5/86 GIFT 5/87

9. How many different patients were stimulated?
1987 IVF 16 1988 IVF ~~15~~ 10
GIFT 28 GIFT ~~20~~ 14

10. How many stimulation cycles were performed?
1987 IVF 19 1988 IVF 14
GIFT 33 GIFT 20

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 15 1988 9

How many embryo transfer cycles were performed?
1987 12 1988 9

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 22 1988 10

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 11 58 % 1988 IVF 8 57 %
GIFT 4 12 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 7 37 % 1988 IVF 3 21 %
GIFT 8 24 % GIFT 5 ~~10~~ %20
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 3 21 %
GIFT 5 15 % GIFT 1 5 %
(d) Unexplained infertility:
1987 IVF 1 5 % 1988 IVF 0 0 %
GIFT 15 46 % GIFT 12 60 %
(e) Other (explain) *(ovulatory dysfunction*1) (** 3 ovulatory dysfunction?)
1987 IVF 0 0 % 1988 IVF 0 0 %
*GIFT 1 3 % **GIFT 3 15 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 2 11 % 1988 IVF 0 0 %
GIFT 6 18 % GIFT 3 21 %
(b) 31-35:
1987 IVF 12 63 % 1988 IVF 4 40 %
GIFT 16 49 % GIFT 2 14 %
(c) 36-40:
1987 IVF 5 26 % 1988 IVF 4 40 %
GIFT 5 15 % GIFT 6 43 %

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 1 10 %
GIFT 6 18 % GIFT 3 21 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 1 10 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 2 1988 IVF 2
GIFT 6 GIFT 2

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 1 1988 IVF 1
GIFT 1 GIFT 5

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 % —
GIFT 0 0 % —

1988 IVF 1 17 % twin reduced to singleton on-going
GIFT 1 17 % twin gestation ongoing

21. What are the qualifications of the director of the embryo laboratory? Pathologist, Director of Clinical LABORATORIES (Board Certified)

22. Who supervises the laboratory director? See #21

23. Does the clinic participate in an external laboratory proficiency testing program? ~~CAP~~ Yes
If the answer is yes, please specify which program.
CAP

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? NO

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Northwest Center for Infertility and Reproductive Endocrinology
ADDRESS: 5800 Colonial Drive, Suite 200
Margate, Florida 33063

CONTACT PERSON: Margie Millard
PHONE NUMBER: (305) 972-5001

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/25/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based X
   (c) University based ______
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   (a) Physicians -
   (b) Laboratory Scientists (PhDs) -
   (c) Nurses 4
   (d) Embryo Lab Technicians/Technologists 3
   (e) Other Lab Technicians/Technologists ______
   (f) Radiology (Ultrasound) Technicians ______
   (g) Psychologists/Counselors 1
   (h) Secretaries 1
   (i) Other (specify) 3 Office Personnel

7. How many years has your infertility clinic been in operation? since 8/1/86

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF July '87 GIFT July '87

9. How many different patients were stimulated?
1987 IVF 24 1988 IVF 79
GIFT 13 GIFT 15

10. How many stimulation cycles were performed?
1987 IVF 28 1988 IVF 106
GIFT 13 GIFT 16

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 20 1988 70

How many embryo transfer cycles were performed?
1987 11 1988 63

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 11 1988 15

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ - ___% 1988 - ___% NONE

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 19 68% 1988 IVF 55 52%
GIFT 1 8% GIFT 0 0%
(b) Endometriosis:
1987 IVF 3 11% 1988 IVF 22 21%
GIFT 6 46% GIFT 9 60%
(c) Male infertility:
1987 IVF 2 7% 1988 IVF 11 10%
GIFT 0 0% GIFT 0 0%
(d) Unexplained infertility:
1987 IVF 2 7% 1988 IVF 6 6%
GIFT 5 39% GIFT 6 40%
(e) Other (explain): ______________________
1987 IVF 2 7% 1988 IVF 12 11%
GIFT 1 7.7% GIFT 0 0%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 14 50% 1988 IVF 32 31%
GIFT 2 15% GIFT 5 33%
(b) 31-35:
1987 IVF 9 32% 1988 IVF 37 35%
GIFT 8 62% GIFT 9 60%
(c) 36-40:
1987 IVF 4 14% 1988 IVF 34 32%
GIFT 3 23% GIFT 1 7%

(d) 41-45:
1987 IVF 1 4 % 1988 IVF 3 3 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 4 1988 IVF 10
GIFT 2 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 3
GIFT 0 GIFT 2

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 3 1988 IVF 6
GIFT 2 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 %
GIFT 0 0 %

1988 IVF 0 0 % All birth so far have been singletons
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? B.S. in Biology, Chemistry minor, 15 Yrs Laboratory experience, including 3 years in 2 other IVF Laboratories

22. Who supervises the laboratory director? Physician Director

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
CAP survey. Voluntary monitoring of IVF by outside experts 2x/ year

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Application Submitted

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 1(GIFT ONLY)
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists 3 (GIFT ONLY)
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Varied patient population ages 24 - 44 years old.

Includes couples with severe male factor infertility and those requiring concomitant operative and laser laparoscopy.

IVF/GIFT SURVEY

CLINIC NAME: University of Miami School of Medicine
ADDRESS: Department of Obstetrics & Gynecology (D-5)
P.O.Box 016960
Miami, FL 33101

CONTACT PERSON: Terry T. Hung, M.D.,Ph.D.
PHONE NUMBER: (305) 547-5818
(305) 547-5849

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   - (a) Physicians 2
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists ______
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors ______
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1985

9. How many different patients were stimulated?
1987 IVF 69   1988 IVF 52
GIFT 8   GIFT 12

10. How many stimulation cycles were performed?
1987 IVF 75   1988 IVF 52
GIFT 8   GIFT 12

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 68   1988 43

How many embryo transfer cycles were performed?
1987 47   1988 35

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 4   1988 9

13. What were the number and percentage of patients on IRB approved research protocols?
1987 - ___%   1988 - ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 60 87%   1988 IVF 41 95%
GIFT 0 0%   GIFT 1 11%
(b) Endometriosis:
1987 IVF 8 11%   1988 IVF 9 21%
GIFT 1 12%   GIFT 2 22%
(c) Male infertility:
1987 IVF 0 0%   1988 IVF 3 7%
GIFT 3 37%   GIFT 1 11%
(d) Unexplained infertility:
1987 IVF 1 1%   1988 IVF 1 2%
GIFT 4 50%   GIFT 4 45%
(e) Other (explain): Anovulation
1987 IVF - ___%   1988 IVF - ___%
GIFT - ___%   GIFT 1 11%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 6 8%   1988 IVF 10 23%
GIFT 0 0%   GIFT 2 22%
(b) 31-35:
1987 IVF 40 58%   1988 IVF 14 28%
GIFT 8 100%   GIFT 3 33%
(c) 36-40:
1987 IVF 23 33%   1988 IVF 25 42%
GIFT 0 0%   GIFT 4 45%

(d) 41-45:
1987 IVF 0 0% 1988 IVF 3 7%
GIFT 0 0 % GIFT - %

(e) >45:
1987 IVF 0 0% 1988 IVF - %
GIFT 0 0 % GIFT - %

16. How many clinical pregnancies were produced?
1987 IVF 4 1988 IVF 6
GIFT - GIFT 2

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 3 1988 IVF 2
GIFT - GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF - 1988 IVF 3
GIFT - GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 25 %
GIFT - - %

1988 IVF 1 16 %
GIFT 1 50 %

21. What are the qualifications of the director of the embryo laboratory? Ob/Gyn Diplomate in Israel. Fellowship in IVF/GIFT - Former Director of IVF Lab in Rehovot Hospital in Israel

22. Who supervises the laboratory director? Clinical Director

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes . If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 3
    (b) Laboratory scientists (PhDs) 4
    (c) Embryo laboratory technicians/technologists 2
    (d) Nurses 3
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: SAND LAKE IVF CENTER
ADDRESS:
9430 TURKEY LAKE
SUITE 218
ORLANDO, FL 32819
CONTACT PERSON: GARY W. DeVANE MD
PHONE NUMBER: (407) 843-0587 or 351-1758

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 1-1989

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or ~~Board Eligible~~ Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians 1 full time 1 part time
   - (b) Laboratory Scientists (PhDs) 2 (consultants)
   - (c) Nurses 4
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 0 (part time consultant)
   - (h) Secretaries 2
   - (i) Other (specify) 1 administrator

7. How many years has your infertility clinic been in operation? 3

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 7-86 GIFT 10-86

9. How many different patients were stimulated?
1987 IVF 75 1988 IVF 118
GIFT 2 GIFT 6

10. How many stimulation cycles were performed?
1987 IVF 89 1988 IVF 143
GIFT 2 GIFT 6

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 74 1988 114

How many embryo transfer cycles were performed?
1987 62 1988 100

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 2 1988 6

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:

N/A

(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) Other (explain): ______________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:

N/A

(a) <31:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(b) 31-35:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(c) 36-40:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 18 1988 IVF 28
GIFT 0 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 10 1988 IVF 9
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 11
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 3
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births? twins only
1987 IVF ___ 29% ________
GIFT ___ 0% ________

1988 IVF ___ 28% ________
GIFT ___ 6% ________

21. What are the qualifications of the director of the embryo laboratory? MASTER DEGREE

22. Who supervises the laboratory director? PhD CONSULTANT

23. Does the clinic participate in an external laboratory proficiency testing program? YES
If the answer is yes, please specify which program.
WATER AND MEDIA PURITY QUALITY QUARTERLY
HOSPITAL BIOMEDICAL ENGINEERING INSPECTION

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? YES

27. Does the clinic train individuals in IVF or GIFT? NO
If the answer is yes, how many individuals in the following specialties have been trained?
   (a) Physicians ______
   (b) Laboratory scientists (PhDs) ______
   (c) Embryo laboratory technicians/technologists ______
   (d) Nurses ______
   (e) Other (explain) ______
VISITORS ARE WELCOMED INCLUDING (a, b, c & d)

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

our clinic soon will be relocated to an ambulatory surgery center future name:

Center for Infertility and Repro-
Ductive Medicine, Orlando.

We have a very successful cryo-preservation program. One patient had 2 previously cryopreserved embryos thawed and placed into her fallopian tubes (modified GIFT) c̄ ultimate delivery of twins. These offsprings did not fit into your categories.

We did not have time to pull charts to confirm Diagnosis - will do at later time if required

Gary H. DeVane

CENTER FOR INFERTILITY AND REPRODUCTIVE MEDICINE (IVF SANDLAKE-ORLANDO)

1988 IVF Data Update

	Egg Recoveries	Clinical Pregnancies	Percentage	Live Births	Continuing Pregnancies
IVF	112	27	24%	9	14
Thawed E.R.	42	8	19%	3*	3
Total	154	35	23%		

*Includes 1 set of twins

IVF/GIFT SURVEY

CLINIC NAME: The Florida Fertility Institute
ADDRESS: 3451 66th Street, North
St. Petersburg, Fl. 33710

CONTACT PERSON: Dr. Thomas L. Alderson
PHONE NUMBER: (813) 384-4000

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 10-1-88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private X
   (b) Community hospital based X
   (c) University based ______
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2 prior to 7-88, One since July, 1988

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   (a) Physicians 5
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 5
   (d) Embryo Lab Technicians/Technologists 1
   (e) Other Lab Technicians/Technologists 1
   (f) Radiology (Ultrasound) Technicians 2
   (g) Psychologists/Counselors 1
   (h) Secretaries 5
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 1¼ years

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 8-87 GIFT 7-87

9. How many different patients were stimulated?
1987 IVF 14 1988 IVF 15
GIFT 29 GIFT 35

10. How many stimulation cycles were performed?
1987 IVF 18 1988 IVF 20
GIFT 33 GIFT 33

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 16 1988 12

How many embryo transfer cycles were performed?
1987 10 1988 10

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 28 1988 29

13. What were the number and percentage of patients on IRB approved research protocols?
1987 100% ___% 1988 100% ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 7 50% 1988 IVF 5 33%
GIFT 8 28% GIFT 7 20%
(b) Endometriosis:
1987 IVF 2 14% 1988 IVF 5 33%
GIFT 10 34% GIFT 13 37%
(c) Male infertility:
1987 IVF 5 36% 1988 IVF 5 33%
GIFT 3 10% GIFT 6 17%
(d) Unexplained infertility:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 8 28% GIFT 9 26%
(e) Other (explain): ___
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 2 2% 1988 IVF 2 2%
GIFT 5 5% GIFT 5 5%
(b) 31-35:
1987 IVF 9 9% 1988 IVF 5 5%
GIFT 15 16% GIFT 21 23%
(c) 36-40:
1987 IVF 2 2% 1988 IVF 4 4%
GIFT 6 6% GIFT 4 4%

(d) 41-45:
1987 IVF 2 2 % 1988 IVF 3 3 %
GIFT 1 1 % GIFT 2 2 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 1 %
GIFT 1 1 % GIFT 0 1 %

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 1
GIFT 5 GIFT 7

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 7

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 5

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 %
GIFT 0 0 %

1988 IVF 0 0 %
GIFT 1 8 % One set of twins

21. What are the qualifications of the director of the embryo laboratory? See attached Cirriculum Vitae
Current PhD candidate

22. Who supervises the laboratory director? Frequent team meetings

23. Does the clinic participate in an external laboratory proficiency testing program? No suitable external program
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Membership pending

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    - (a) Physicians ________
    - (b) Laboratory scientists (PhDs) _______
    - (c) Embryo laboratory technicians/technologists _____
    - (d) Nurses _______
    - (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Due to the limited number of total IVF procedures we have done, our successes are greatly influenced by women over the age of 36 and those women who are poor responders.

IVF/GIFT SURVEY

CLINIC NAME: HUMANA WOMEN'S HOSPITAL/ UNIV. SOUTH FLORIDA
ADDRESS: 3030 W. Buffalo Ave
Tampa, Florida 33606

CONTACT PERSON: Dr. George B. Maroulis
PHONE NUMBER: 813-872-2988 or 813-251-7269

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? December 20, 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based ______
   - (d) Other (explain) Private (Humana) in cooperation with the Univer. of South Florida's Dept of OB-GYN and Pediatrics

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 6

6. How many other professionals participate in your clinic?
   - (a) Physicians 5
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 3
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors ----
   - (h) Secretaries 1
   - (i) Other (specify) ----.

7. How many years has your infertility clinic been in operation? 3

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF Jan. 1986 GIFT October 1986

9. How many different patients were stimulated?
1987 IVF 52 1988 IVF 62
GIFT 3 GIFT 21

10. How many stimulation cycles were performed?
1987 IVF 62 1988 IVF 89
GIFT 3 GIFT 26

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 44 1988 59

How many embryo transfer cycles were performed?
1987 34 1988 43

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 2 1988 19

13. What were the number and percentage of patients on IRB approved research protocols?
1987 25 45 % 1988 77 93 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 29 56 % 1988 IVF 40 64 %
GIFT 0 0 % GIFT 3 14 %
(b) Endometriosis:
1987 IVF 5 10 % 1988 IVF 13 21 %
GIFT 0 0 % GIFT 8 38 %
(c) Male infertility:
1987 IVF 1 2 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 1 5 %
(d) Unexplained infertility:
1987 IVF 4 8 % 1988 IVF 6 10 %
GIFT 2 66 % GIFT 8 38 %
(e) Other (explain): Anovulation
1987 IVF 13 24 % 1988 IVF 3 5 %
GIFT 1 34 % GIFT 1 5 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 12 23 % 1988 IVF 13 21 %
GIFT 0 0 % GIFT 3 14 %
(b) 31-35:
1987 IVF 21 40 % 1988 IVF 24 39 %
GIFT 1 34 % GIFT 10 47 %
(c) 36-40:
1987 IVF 17 33 % 1988 IVF 23 37 %
GIFT 2 66 % GIFT 7 34 %

(d) 41-45:
1987 IVF 2 4 % 1988 IVF 2 3 %
GIFT 0 0 % GIFT 1 5 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 7 1988 IVF 8
GIFT 1 GIFT 6

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 6 1988 IVF 6
GIFT 0 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 6
GIFT 0 GIFT 6

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 29 % 1 Set Twins, 1 set triplets
GIFT 0 0 %

1988 IVF 0 0 %
GIFT 1 15 % 1 Set of Triplets

21. What are the qualifications of the director of the embryo laboratory? PH.D in Genetics; Special training in IVF and Embryo cultures at East Virginia Medical School in Norfolk

22. Who supervises the laboratory director? Dr. Maroulis, Dr. Verkauf

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
CAP Proficiency Testing Ligand Assay Series 2 (1988)

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Not at the present, However a Fellowship program is planned to be started at the University of South Florida Dept of OB-GYN.

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? xxxxxYes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?

- **(a) Physicians** ________
- **(b) Laboratory scientists (PhDs)** ________
- **(c) Embryo laboratory technicians/technologists** 3
- **(d) Nurses** 2
- **(e) Other (explain)** ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Our Clinic started on Jan. 1, 1986. Since then we have consistently maintained a pregnancy rate of 20-25% per transfer for IVF and 30-35% for GIFT. Most of our population is from the Tampa Bay area, and the West Coast of Florida. We are currently in the process of initiating an embryo and oocyte freezing program as well as an oocyte donation program. Our program is a cooperative effort between a.) Humana Women's Hospital which provides the personnel and facilities. b.) The Department of Obstetrics and Gynecology and Pediatrics of the University of South Florida, which have provided the expertise for establishing the Embryo, Andrology and Radioimmunoassay Laboratories as well as providing patients, and research activities. c.) Physicians in the community which have provided patients and who participate in the actual procedures for IVF and GIFT.

At the present time we anticipate to enter 61 patients for IVF or GIFT during the months of January and February.

This program is active in research activities and up to now a number of papers have been presented to the American Fertility Society's meetings in 1986,1987,and 1988.

IVF/GIFT SURVEY

CLINIC NAME: Reproductive Biology Associates
ADDRESS: 993-D Johnson Ferry Rd.
Suite 330
Atlanta Georgia 30342

CONTACT PERSON: Lucretia Minor
PHONE NUMBER: (404) 843-3064

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12-88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    (a) Private ✓
    (b) Community hospital based ______
    (c) University based ______
    (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 5 (including 3 above)

6. How many other professionals participate in your clinic?
    (a) Physicians 3
    (b) Laboratory Scientists (PhDs) 1
    (c) Nurses 4
    (d) Embryo Lab Technicians/Technologists 3
    (e) Other Lab Technicians/Technologists 2
    (f) Radiology (Ultrasound) Technicians 2
    (g) Psychologists/Counselors 1
    (h) Secretaries 2
    (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 4+

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1986

- 2 -

9. How many different patients were stimulated?
1987 IVF 224 1988 IVF 219
GIFT 9 GIFT 38

10. How many stimulation cycles were performed?
1987 IVF 224 1988 IVF 1 334
GIFT 47 GIFT 1 58

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 156 15 1988 227

How many embryo transfer cycles were performed?
1987 145 -5 1988 176

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 9 1988 34

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 30 13 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 66 30 % 1988 IVF 90 42 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 94 42 % 1988 IVF 131 38 %
GIFT 5 55 % GIFT 0 0 %
(c) Male infertility:
1987 IVF 48 21 % 1988 IVF 83 35 %
GIFT 0 0 % GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 17 8 % 1988 IVF 36 11 %
GIFT 4 44 % GIFT 20 51 %
(e) Other (explain): NO DES Exposure, etc.
1987 IVF 2 1 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 18 49 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 21 9 % 1988 IVF 34 15 %
GIFT 2 22 % GIFT 11 29 %
(b) 31-35:
1987 IVF 73 33 % 1988 IVF 98 41 %
GIFT 3 33 % GIFT 20 53 %
(c) 36-40:
1987 IVF 102 46 % 1988 IVF 79 33 %
GIFT 4 44 % GIFT 5 13 %

(d) 41-45:
1987 IVF 28 13% 1988 IVF 21 9%
GIFT 0 0% GIFT 5 13%

(e) >45:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 0 0%

16. How many clinical pregnancies were produced? *
1987 IVF 33 1988 IVF 56 See Appendix
GIFT 3 GIFT 6

17. How many women delivered live infants from IVF/GIFT? *
1987 IVF 29 1988 IVF 11 See Appendix
GIFT 2 GIFT 3

18. How many women have continuing pregnancies from IVF/GIFT? *
1987 IVF 0 1988 IVF 45 See Appendix
GIFT 0 GIFT 3

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 3 10% Twins
GIFT 1 33% Twins

1988 IVF 4 36% Twins
GIFT 0 0% —

21. What are the qualifications of the director of the embryo laboratory? 3 years experience directing Bourne Hall Laboratory England. 2 years Scientific Director with Reproductive Biology Associates.

22. Who supervises the laboratory director? ______________

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes.
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists 45-50
    (d) Nurses ________
    (e) Other (explain) *

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

See Attached Letter.

APPENDIX

16. How many clinical pregnancies were produced?

1987 IVF*
Fresh Cycle = 33
Including cryopreservation cycles = 45
GIFT = 3

198|8 IVF
Fresh cycle = 56
Including cryopreservation cycles = 76
GIFT = 6

17. How many women delivered live infants from IVF/GIFT?

1987 Fresh cycle = 29
Including cryopreservation cycles = 41
GIFT = 2

1988 Fresh cycle = 11
Including cryopreservation cycles = 15
GIFT = 3

18. How many women have continuing pregnancies from IVF/GIFT?

1987 = 0

1988 Fresh cycle = 45
Including cryopreservation cycles = 61
GIFT = 3

ATTACHED LETTER

As the leading center for embryo cryopreservation in the country, we have offered cryopreservation workshops on 3 occasions. Approximately 45 people have attended these workshops.

As we are the first clinic to improve fertilization rates in male infertility by micromanipulation of human eggs, we are now soliciting participants in microsurgical workshops introducing our techniques of partial zona dissection. We have offered to teach this technique in small tutorial sessions in 1989.

**REPRODUCTIVE
BIOLOGY
ASSOCIATES**

993 D Johnson Ferry Road
Suite 330
Atlanta, Georgia 30342
404 843 3064

Jacques Cohen PhD
Carlene W. Elsner MD
Hilton I. Kort MD
Joe B. Massey MD

December 13, 1988

Congressman Ron Wyden, Chairman
Subcommittee on Regulation and
Business Opportunities
Suite 1406
Longworth House Office Building
Washington, D.C. 20515

Dear Honorable Congressman Wyden:

We appreciate the efforts of the Subcommittee on Regulation and Business Opportunities to review the state of infertility treatment in this country.

At the recent meeting of the Society for Assisted Reproductive Technology, we urged publication of individual clinic statistics. The other members of this Society agree that your leadership has provided the necessary impetus required to assure that such reporting will be carried out in a timely fashion and that the results will be made available to the public.

As you will notice, we have included in our results our experience with embryo cryopreservation and the impact of cryopreservation on pregnancy results per stimulated cycle and per egg retrieval. The most important statistic is the delivered pregnancy rate per retrieval which has been colloquially referred to as the "take home baby rate". This is very profoundly influenced by cryopreservation. We also strongly believe that the expression of success should be expressed in the total likelihood of pregnancy resulting from a single egg retrieval since most of the time, financial costs, discomfort and risks are involved in stimulating the ovary, monitoring the response abd retrieving the eggs. Approximately 50% of our patients now have embryos preserved increasing significantly their chances of pregnancy.

We urge you therefore to include the total likelihood of success per cycle including cryopreservation, in your report. This may be opposed by others since few clinics in this country have devoted themselves to improving this important aspect of IVF technology.

Although we are in full support of your efforts to oversee IVF laboratories, the question is how to accomplish this efficiently and fairly. We are unaware of objective measures which can predict the success of in vitro fertilization.

Again, thank you for your dilligence and persistence in pursuing these issues.

Sincerely,

Jacques Cohen, Ph.D.
Carlene Elsner MD
Carlene W. Elsner, M.D.
Kort
Hilton I. Kort, M.D.
Joe B. Massey, M.D.
D Mitchell
Dorothy Mitchell, M.D.
A Toledo
Andrew Toledo, M.D.

IVF/GIFT SURVEY

CLINIC NAME: Augusta Reproductive Biology Associates
ADDRESS:
810-812 Chafee Avenue
Augusta GA 30904

CONTACT PERSON: Edward T. Seavy M.D.
PHONE NUMBER: (404) 724-0228.

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the never clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Dec. 14, 1988

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private X
   (b) Community hospital based X
   (c) University based ________
   (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 0

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   (a) Physicians 3
   (b) Laboratory Scientists (PhDs) 3
   (c) Nurses 3
   (d) Embryo Lab Technicians/Technologists 2
   (e) Other Lab Technicians/Technologists 1
   (f) Radiology (Ultrasound) Technicians 1
   (g) Psychologists/Counselors 1
   (h) Secretaries 2
   (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 13 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 1984 GIFT —

9. How many different patients were stimulated?
1987 IVF 24 1988 IVF 30
GIFT ___ GIFT ___

10. How many stimulation cycles were performed?
1987 IVF 25 1988 IVF 36
GIFT ___ GIFT ___

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 24 1988 32

How many embryo transfer cycles were performed?
1987 18 1988 21

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 24 100% 1988 30 100%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 17 70% 1988 IVF 19 63%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 1 4% 1988 IVF 3 10%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF 2 8% 1988 IVF 2 7%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF 4 17% 1988 IVF 5 17%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): LUF Syndrome
1987 IVF ___ ___% 1988 IVF 1 3%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 10 42% 1988 IVF 12 40%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF 11 46% 1988 IVF 12 40%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF 2 8% 1988 IVF 6 20%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF 1 4% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 6 1988 IVF 7
GIFT ___ GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 1 1988 IVF 5
GIFT ___ GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 4 1988 IVF 7
GIFT ___ GIFT ___

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT ___ GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 4% single
GIFT ___ ___% ______

1988 IVF 5 16.4% All single pregnancies
GIFT ___ ___% ______

21. What are the qualifications of the director of the embryo laboratory? #1 PhD in Anatomy and Embryology
#2 MD Pathologist

22. Who supervises the laboratory director? Community Hospital IVF Committee

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
______

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** NO

27. **Does the clinic train individuals in IVF or GIFT?** Yes **If the answer is yes, how many individuals in the following specialties have been trained?**
    - **(a) Physicians** 4
    - **(b) Laboratory scientists (PhDs)** 2
    - **(c) Embryo laboratory technicians/technologists** 2
    - **(d) Nurses** 3
    - **(e) Other (explain)** ______

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

Request for membership of the SART was made, but it was refused because we did not have more than 40 combined GIFT and IVF cases a year. Membership should be based on quality and not on quantity. We will apply again.

Our reproductive endocrinology and infertility practice, clinic and laboratory are thirteen years old. The IVF portion of the practice was redesigned in July of 1987. No IVF was performed between January and July of this year because of the new construction and structural changes. Therefore, our results do not really reflect six months of IVF work per year.

IVF and GIFT should not be compared or evaluated at the same level. IVF provida irreplaceable way to overcome the lack or deficit of the fallopian tubes. GIFT is controversial and can be replaced by less stressful and/or less expensive methods.

We suggest for the consumer's sake that legislation or regulation of the embryology laboratories should also address the quality of andrology and hormone assays provided by the lab. They are also a part of the same entity.

Finally, efforts should be made by the subcommittee to include among their consultants, physicians and/or embryologists from the private sector. The private clinics have already helped much to improve scientific progress, quality of care and cost effectiveness. They should not be left aside.

IVF/GIFT SURVEY

CLINIC NAME: Medical College of Georgia
ADDRESS: IVF Program
Dept. Ob-Gyn, CK-157
Augusta, Georgia 30912

CONTACT PERSON: Leo Plouffe, M.D.
PHONE NUMBER: (904) 721-3832

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12-15-88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 5

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 9

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 4

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 12/84 GIFT 5/86

9. How many different patients were stimulated?
1987 IVF 19 1988 IVF 26
GIFT 1 GIFT 4

10. How many stimulation cycles were performed?
1987 IVF 25 1988 IVF 35
GIFT 1 GIFT 4

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 14 1988 19

How many embryo transfer cycles were performed?
1987 11 1988 16

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 2

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0 % 1988 ___ 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
13/68% 1987 IVF 6 8 % 1988 IVF 6 2 % 16/62%
GIFT — % GIFT ___ 0 % 0
(b) Endometriosis:
3/16% 1987 IVF 1 6 % 1988 IVF 0 8 % ← 2/8%
GIFT — % GIFT 2 5 % 1/25%
(c) Male infertility:
3/16% 1987 IVF 1 6 % 1988 IVF 2 2 % 6/22%
GIFT — % GIFT 2 5 % 1/25%
(d) Unexplained Infertility:
1987 IVF ___ 0 % 1988 IVF 0 8 % 2/8%
GIFT — % GIFT 2 5 % 1/25%
(e) Other (explain): Cervical
1/100% 1987 IVF ___ 0 % 1988 IVF ___ 0 %
GIFT 100 % GIFT 2 5 % 1/25%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 3 7 % 1988 IVF 2 2 % 6/22%
GIFT — % GIFT 2 5 % 1/25%
(b) 31-35:
1987 IVF 2 6 % 1988 IVF 5 6 % 14/56%
GIFT 100 % GIFT 5 0 % 2/50%
(c) 36-40:
1987 IVF 3 7 % 1988 IVF 2 2 % 6/22%
GIFT — % GIFT 2 5 % 1/25%

(d) 41-45:
1987 IVF — % 1988 IVF — %
GIFT — % GIFT — %

(e) >45:
1987 IVF — % 1988 IVF — %
GIFT — % GIFT — %

16. How many clinical pregnancies were produced?
1987 IVF 4 1988 IVF 3
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 3 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 5 % 1 set of twins / 4 pregnancies
GIFT — %

1988 IVF 3 3 % 1 set of twins / 3 pregnancies
GIFT — %

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Anatomy; 2 years Supervised experience in IVF lab of established successful program; Ongoing genetic research; 4 years experience in our IVF lab

22. Who supervises the laboratory director? Section chief

23. Does the clinic participate in an external laboratory proficiency testing program? yes
If the answer is yes, please specify which program.
CAP: Y series

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? ✓

26. Is the clinic a member of the Society for Assisted Reproductive Technology? yes

27. Does the clinic train individuals in IVF or GIFT? no
If the answer is yes, how many individuals in the following specialties have been trained?
   (a) Physicians ____
   (b) Laboratory scientists (PhDs) ____
   (c) Embryo laboratory technicians/technologists ____
   (d) Nurses ____
   (e) Other (explain) ____

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Many of our patients have multifactorial infertility. Diagnosis was calculated on basis of major etiology.

Three of eight women who have received thawed embryo transfer have become pregnant. One has delivered, one aborted ~ 8 wks., one is pregnant now ~ 7 wks. A ninth woman recently received a transfer of 2 thawed embryos, but the pregnancy test will be done 12-30-88

IVF/GIFT SURVEY

CLINIC NAME: Pacific In Vitro Fertilization Institute
ADDRESS: 1319 Punahou Street Suite 1040
Honolulu, Hawaii 96826

CONTACT PERSON: Dr. Philip McNamee, Director or Lisa Ontai, R.N., Nurse Coordinator
PHONE NUMBER: (808) 946-2226

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/1/88

2. Does your clinic perform IVF/GIFT treatments? Yes - IVF only
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    (a) Private X
    (b) Community hospital based ________
    (c) University based ________
    (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 5

6. How many other professionals participate in your clinic?
    (a) Physicians 5
    (b) Laboratory Scientists (PhDs) 1
    (c) Nurses 2
    (d) Embryo Lab Technicians/Technologists 2
    (e) Other Lab Technicians/Technologists ________
    (f) Radiology (Ultrasound) Technicians ________
    (g) Psychologists/Counselors 1 (On referral basis)
    (h) Secretaries 1
    (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 3 3/4 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
    IVF March 1985 GIFT ________

9. How many different patients were stimulated?
1987 IVF 34 1988 IVF 105
GIFT ____ GIFT ____

10. How many stimulation cycles were performed?
1987 IVF 37 1988 IVF 120
GIFT ____ GIFT ____

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 27 1988 88

How many embryo transfer cycles were performed?
1987 26 1988 82

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ____ 1988 ____

13. What were the number and percentage of patients on IRB approved research protocols?
1987 N/A % 1988 N/A %

14. What were the number and percentage of patients* treated for:
(a) Tubal factor:
1987 IVF 21 56 % 1988 IVF 72 60 %
GIFT ___ ___ % GIFT ___ ___ %
(b) Endometriosis:
1987 IVF 7 19 % 1988 IVF 20 17 %
GIFT ___ ___ % GIFT ___ ___ %
(c) Male infertility:
1987 IVF 6 16 % 1988 IVF 10 12 %
GIFT ___ ___ % GIFT ___ ___ %
(d) Unexplained infertility:
1987 IVF 2 5 % 1988 IVF 16 13 %
GIFT ___ ___ % GIFT ___ ___ %
(e) Other (explain): annovulation (4) sperm antibodies (1)
1987 IVF 0 0 % 1988 IVF 5 4 %
GIFT ___ ___ % GIFT ___ ___ %

*Some patients had more than one factor.

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 6 18 % 1988 IVF 21 20 %
GIFT ___ ___ % GIFT ___ ___ %
(b) 31-35:
1987 IVF 8 24 % 1988 IVF 31 30 %
GIFT ___ ___ % GIFT ___ ___ %
(c) 36-40:
1987 IVF 20 58 % 1988 IVF 53 50 %
GIFT ___ ___ % GIFT ___ ___ %

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 5 1988 IVF 23
GIFT ___ GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 5 1988 IVF 10
GIFT ___ GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 8
GIFT ___ GIFT ___

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 2
GIFT ___ GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 20% 1 set: twins
GIFT ___ ___%

1988 IVF 11 44% 6 sets: twins 3 sets: triplets
GIFT ___ ___% 1 set: quads 1 set: quints

21. What are the qualifications of the director of the embryo laboratory? PhD in cell biology; 7 years IVF experience in animals; 6 years IVF in humans

22. Who supervises the laboratory director? The Director of the In Vitro Fertilization Institute

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Application submitted & pending

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
- **(a) Physicians** ______
- **(b) Laboratory scientists (PhDs)** 1
- **(c) Embryo laboratory technicians/technologists** 1
- **(d) Nurses** 2
- **(e) Other (explain)** ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The Pacific In Vitro Fertilization Institute (PIFI) has provided infertility services for Hawaii since 1985, when we established the first successful IVF pregnancy in the state. Since then, our IVF program has been among the most successful in the nation, with a clinical pregnancy rate per transfer of 30% and a projected take-home baby rate of 23% in 1988. Our location makes us a referral center for the Pacific Rim community in addition to the entire population of Hawaii. PIFI now has facilities solely dedicated to IVF and other infertility procedures such IUI, embryo, and sperm freezing.

Since PIFI serves a large geographical region, our stimulation protocols are devised to allow patients to undergo hormone stimulations for IVF at home. Patients need to come to PIFI beginning on Day 9 of their cycle. Arrangements can be made for economical stay at a nearby hotel. Moreover, for patient convenience and economy, egg retrievals are routinely performed ultrasonographically, as an outpatient procedure. Patients who reside in Hawaii now have limited insurance coverage for IVF. Our institute is located at Kapiolani Medical Center for Women and Children, Suite 1040,
1319 Punahou Street
Honolulu, Hawaii 96826

Telephone: (808) 946-2226
Contact: Dr. Philip McNamee or Lisa Ontai, R.N.

IVF/GIFT SURVEY

CLINIC NAME: Division of Reproductive Endocrinology and Infertility

ADDRESS: Kauai Medical Group
3420 B. Kuhio Highway
Lihue, HI 96766

CONTACT PERSON: Frederick Sorgstacke II M.D. (Director)

PHONE NUMBER: (808) 245-1511 or 245-1521 or 245-1516

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 1988 only

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? One

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? Four

6. How many other professionals participate in your clinic?
   - (a) Physicians Two
   - (b) Laboratory Scientists (PhDs) One
   - (c) Nurses One
   - (d) Embryo Lab Technicians/Technologists One
   - (e) Other Lab Technicians/Technologists One
   - (f) Radiology (Ultrasound) Technicians Two
   - (g) Psychologists/Counselors One
   - (h) Secretaries Two
   - (i) Other (specify) Not applicable

7. How many years has your infertility clinic been in operation? 6 (Six)

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1985 GIFT 1987

9. How many different patients were stimulated?
N/A 1987 IVF ______ 1988 IVF 5
GIFT ______ GIFT 5

10. How many stimulation cycles were performed?
N/A 1987 IVF ______ 1988 IVF 5
GIFT ______ GIFT 5

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
N/A 1987 ________ 1988 5

How many embryo transfer cycles were performed?
N/A 1987 ________ 1988 5

12. How many GIFT procedures (attempted egg recoveries) were performed?
N/A 1987 ________ 1988 5

13. What were the number and percentage of patients on IRB approved research protocols?
N/A 1987 ___ ___% 1988 None ___%

14. What were the number and percentage of patients treated for:

(a) Tubal factor:
N/A 1987 IVF ___ ___% 1988 IVF 3 60 %
GIFT ___ ___% GIFT 0 ___%

(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 0 ___%
N/A GIFT ___ ___% GIFT 0 ___%

(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 2 40 %
N/A GIFT ___ ___% GIFT 5 100 %

(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF 0 ___%
N/A GIFT ___ ___% GIFT 0 ___%

(e) Other (explain): ____________________
1987 IVF ___ ___% 1988 IVF 0 %
N/A GIFT ___ ___% GIFT 0 ___%

15. What were the number and percentage of patients in the following age groups:

(a) <31:
1987 IVF ___ ___% 1988 IVF 3 60 %
N/A GIFT ___ ___% GIFT 5 100 %

(b) 31-35:
1987 IVF ___ ___% 1988 IVF 1 20 %
N/A GIFT ___ ___% GIFT 0 ___%

(c) 36-40:
1987 IVF ___ ___% 1988 IVF 1 20 %
N/A GIFT ___ ___% GIFT 0 ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF 0 ___%
N/A GIFT ___ ___% GIFT 0 ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF 0 ___%
NA GIFT ___ ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF ___ 1988 IVF 1 (one) - Pregnancy Aborted
N/A GIFT ___ GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF 0
N/A GIFT ___ GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 0
N/A GIFT ___ GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF 0
N/A GIFT ___ GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ______________
N/A GIFT ___ ___% ______________

1988 IVF ___ ___% N/A
GIFT ___ ___% ______________

21. What are the qualifications of the director of the embryo laboratory? Reproductive Endocrinologist (M.D.)

22. Who supervises the laboratory director? ① AFS Guidelines
② ~~Hospital Professional Activities~~ Committee

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Not at Present

27. Does the clinic train individuals in IVF or GIFT? NO
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ________
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

(See attached Letter)

KAUAI MEDICAL GROUP, INC.

3420-B KUHIO HIGHWAY • LIHUE, HAWAII 96766

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Hector R. Riquel, M.D.
PATHOLOGY
Jonathan Charles, M.D.
Ron D. Couch, M.D.
Gerald S. Tomory, M.D.
PEDIATRICS
Gary M. Cameron, M.D.
Lee A. Evslin, M.D.
Jon B. Gordon, M.D.
Gen O.L. Young, M.D.
PSYCHIATRY
Gerald J. McKenna, M.D.
RADIOLOGY
Clarence H. Furuta, M.D.
Harvey T. Nakamura, M.D.
Jeffrey Y. Sun, M.D.
REPRODUCTIVE ENDOCRINOLOGY
& INFERTILITY
Frederick D. Sengstacke II, M.D.
SURGERY
Thatcher Magoun, M.D.
William L. Brenkel, M.D.
UROLOGY
Vincent Orlando, M.D.
URGENT CARE
Lawrence A. Gordon, M.D.
•
CHIEF OPERATIONS OFFICER
Melvin D. Rieger
CONTROLLER
Pat [illegible]
CLINIC OPERATIONS OFFICER
Dan Hutchinson
•
6 CONVENIENT LOCATIONS
Main Clinic .... [illegible]
3420-B Kuhio Highway, Lihue
[illegible] Clinic (Coconut Beach Area) .... [illegible]
[illegible] Clinic ([illegible] Area) .... [illegible]
[illegible]
Ambulatory Surgery Center .... [illegible]
[illegible] .... [illegible]
Eye Care Center .... [illegible]
Psychiatry .... [illegible]
Rehabilitation Services Center .... [illegible]
North Shore Clinic .... [illegible]
[illegible] Clinic .... [illegible]

February 14, 1989

Congressman Ron Wyden
c/o Committee on Small Business
Subcommittee on Regulation and Business Opportunities
B-363 Rayburn Office Building
Washington, DC 20515

Dear Congressman Wyden:

Thank you for the questionnaire regarding our in vitro fertilization and GIFT Programs.

Our medical Group is currently building a new clinic facility and, therefore, much of my in vitro fertilization work has been postponed until we move our lab into the new building.

All of the in vitro fertilization work done prior to 1988 involved combined in vitro fertilization with reconstructive pelvic surgery in patients with Fallopian tube disease. Therefore, my statistics prior to 1988 are not purely statistics involving in vitro fertilization. Therefore, I will only report on the cases performed during the year of 1988.

I was on sabbatical leave in Japan for a large segment of 1988 and, therefore, only five in vitro fertilization procedures and five GIFT procedures were performed. During January through May of 1988, one GIFT and one in vitro fertilization procedure was performed each month. The in vitro fertilization procedure performed in May of 1988 resulted in a clinical pregnancy. Unfortunately, this patient was assaulted and spontaneously aborted the pregnancy. The spontaneous abortion was associated with the assault and not with the procedure itself. Therefore, the clinical pregnancy rate for 1988 was 20% for in vitro fertilization and 0% for the GIFT procedure.

Many of the patients that I see have both male and female infertility factors. Some have undergone fertility treatments and in vitro fertilization in other clinics without success.

My patient population is relatively small considering the fact that the island of Kauai has approximately 40,000-50,000 permanent residents. However, we have state of the art facilities and equipment available for these advanced reproductive procedures.

Since I am only one of a few practicing obstetrician/gynecologist on Kauai, I practice both general obstetrics & gynecology as well as my subspeciality in reproductive endocrinology and infertility. I am Board eligible in my subspecialty and certified in my speciality. My approach has been to provide a unique and personalized program for patients in a small community hospital setting instead of a large university-based program. Obviously, this has it's advantages and disadvantages. However, due to patient demand, we will continue to make this service available to the patients in our population as long as it can be done with quality and precision. Once the new clinic is built, towards the end of this year, I anticipate that one in vitro fertilization and/or GIFT procedure will be performed each week. I am not discouraged by the small number of patients who ultimately become pregnant with these procedures considering the recently reported statistic of only 16% pregnancy rates in the American Fertility Society's In Vitro Fertilization Registry Survey.

All patients who are counseled regarding this procedure are given the statistics and are offered the opportunity to go off-island and receive care in a university setting if they so desire. However, many of our patients would prefer to remain on Kauai for these procedures.

As long as there is a need, we will try to provide the service for the patients.

Sincerely,

FREDERICK D. SENGSTACKE II, M.D.
Chief of Division of Reproductive Endocrinology & Infertility
Department of OB/GYN
Assistant Clinical Professor, University of Hawaii, College of Medicine

FDS:laf

IVF/GIFT SURVEY

CLINIC NAME: Northwestern Memorial Hospital

ADDRESS: Prentice Women's Hospital
333 E. Superior St.
Chicago, IL 60611

CONTACT PERSON: David I. Hoffman, M.D. & Ms. Margaret Rossiano, R.N., Coordinator

PHONE NUMBER: 312- 908-1364

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. **The following data is current through what date?** 12-14-88

2. **Does your clinic perform IVF/GIFT treatments?** Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. **What type of clinic do you operate? (Place X in appropriate space)**
   - **(a) Private** _____
   - **(b) Community hospital based** _____
   - **(c) University based** X
   - **(d) Other (explain)** _____

4. **How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic?** 3

5. **How many Board Certified Obstetricians/Gynecologists participate in your clinic?** 4

6. **How many other professionals participate in your clinic?**
   - **(a) Physicians** _____
   - **(b) Laboratory Scientists (PhDs)** 1
   - **(c) Nurses** 2
   - **(d) Embryo Lab Technicians/Technologists** 1
   - **(e) Other Lab Technicians/Technologists** 1
   - **(f) Radiology (Ultrasound) Technicians** _____
   - **(g) Psychologists/Counselors** _____
   - **(h) Secretaries** 1
   - **(i) Other (specify)** _____

7. **How many years has your infertility clinic been in operation?** 2 plus years

8. **When were the clinic's first IVF/GIFT stimulation cycles?**
IVF 1987 **GIFT** 1987

9. How many different patients were stimulated?
1987 IVF 30 1988 IVF 15
GIFT 26 GIFT 43

10. How many stimulation cycles were performed?
1987 IVF 35 1988 IVF 18
GIFT 28 GIFT 49

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 27 1988 11

How many embryo transfer cycles were performed?
1987 24 1988 11

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 20 1988 40

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 24 80 % 1988 IVF 15 100%
GIFT 0 ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF 1 3.3 % 1988 IVF 0 ___%
GIFT 7 26.9 % GIFT 13 30.2 %
(c) Male infertility:
1987 IVF 3 10 % 1988 IVF 0 ___%
GIFT 8 30.8 % GIFT 8 18.6 %
(d) Unexplained infertility:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 3 11.5 % GIFT 18 41.9 %
(e) Other (explain): Ovulatory Dysfunction
1987 IVF 2 6.7% 1988 IVF 0 ___%
GIFT 8 30.8 % GIFT 4 9.3 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 4 13.3% 1988 IVF 3 20 %
GIFT 5 19.2 % GIFT 7 16.3 %
(b) 31-35:
1987 IVF 16 53.4% 1988 IVF 9 60 %
GIFT 11 42.3 % GIFT 17 39.5 %
(c) 36-40:
1987 IVF 9 30 % 1988 IVF 3 20 %
GIFT 10 38.5 % GIFT 18 41.9 %

(d) 41-45:
1987 IVF 1 3.3 % 1988 IVF 0 %
GIFT 0 % GIFT 2.1 %

(e) >45:
1987 IVF 0 % 1988 IVF 0 %
GIFT 0 % GIFT 0 %

16. How many clinical pregnancies were produced?
1987 IVF 6 1988 IVF 3
GIFT 8 GIFT 14

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 4
GIFT 0 GIFT 13

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 8

19. How many ectopic pregnancies resulted?
1987 IVF 2 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 %
GIFT 0 0 %

1988 IVF 0 0 % All Singletons
GIFT 6 46 % 5 twins, 1 triplets

21. What are the qualifications of the director of the embryo laboratory?

22. Who supervises the laboratory director? Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 2
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists 2
    (d) Nurses 2
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. These comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

1. Program closed due to hospital construction 6/88 until approximately 3 or 4/89.

2. Gift couples outnumber IVF couples 3:1.

IVF/GIFT SURVEY

CLINIC NAME: UNIVERSITY OF ILLINOIS MEDICAL CENTER
ADDRESS: DEPT OF OB/GYN M/C 808
840 S WOOD
CHICAGO, ILLINOIS
60612
CONTACT PERSON: GERRI ALEXANDER RN IVF NURSE COORDINATOR
PHONE NUMBER: 312 - 996 - 7388

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 10/31/1988

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private
   - (b) Community hospital based
   - (c) University based X
   - (d) Other (explain)

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 4

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians 5
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists -0-
   - (e) Other Lab Technicians/Technologists -0-
   - (f) Radiology (Ultrasound) Technicians -0-
   - (g) Psychologists/Counselors -0-
   - (h) Secretaries 1
   - (i) Other (specify) Nurses in OR - 3

7. How many years has your infertility clinic been in operation? 9

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 11/84 GIFT 11/86

9. How many different patients were stimulated?
1987 IVF 7 1988 IVF 5
GIFT 3 GIFT 2

10. How many stimulation cycles were performed?
1987 IVF 14 1988 IVF 7
GIFT 3 GIFT 2

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 9 1988 5

How many embryo transfer cycles were performed?
1987 4 1988 3

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 2

13. What were the number and percentage of patients on IRB approved research protocols?
1987 -0- % 1988 -0- %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
6/86% 1987 IVF 86 % 1988 IVF 60 % 3/60%
GIFT -0- % GIFT -0- %
(b) Endometriosis:
1987 IVF -0- % 1988 IVF -0- %
2/67% GIFT 67 % GIFT 50 % 1/50%
(c) Male infertility:
1/14% 1987 IVF 14 % 1988 IVF 20 % 1/20%
GIFT -0- % GIFT 60 % 1/80%
(d) Unexplained infertility:
1987 IVF -0- % 1988 IVF 20 % 1/20%
1/33% GIFT 33 % GIFT -0- %
(e) Other (explain): ____________________
1987 IVF -0- % 1988 IVF -0- %
GIFT -0- % GIFT -0- %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
4/67% 1987 IVF 57 % 1988 IVF 20 % 1
1/33% GIFT 33 % GIFT 100 % 2
(b) 31-35:
3/43% 1987 IVF 43 % 1988 IVF 80 % 4
1/33% GIFT 33 % GIFT -0- %
(c) 36-40:
1987 IVF -0- % 1988 IVF -0- %
1/33% GIFT 33 % GIFT -0- %

(d) 41-45:
1987 IVF -0- % 1988 IVF -0- %
GIFT -0- % GIFT -0- %

(e) >45:
1987 IVF -0- % 1988 IVF -0- %
GIFT -0- % GIFT -0- %

16. How many clinical pregnancies were produced?
1987 IVF -0- 1988 IVF -0-
GIFT -0- GIFT -0-

17. How many women delivered live infants from IVF/GIFT?
1987 IVF -0- 1988 IVF -0-
GIFT -0- GIFT -0-

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF -0- 1988 IVF -0-
GIFT -0- GIFT -0-

19. How many ectopic pregnancies resulted?
1987 IVF -0- 1988 IVF -0-
GIFT -0- GIFT -0-

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF -0- % ______________________
GIFT -0- % ______________________

1988 IVF -0- % ______________________
GIFT -0- % ______________________

21. What are the qualifications of the director of the embryo laboratory? Ph.D.

22. Who supervises the laboratory director? Director of Division of Reproductive Endocrinology

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? YES

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? NO (Too many unnecessary societies)

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 3
    (b) Laboratory scientists (PhDs) —0—
    (c) Embryo laboratory technicians/technologists —0—
    (d) Nurses 2
    (e) Other (explain) —1—

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Low volume due to poor neighbourhood
- state (civil service) institution with poor support staff
- we use strict criteria for medical eligibility for GIFT and IVF.
- too many other clinics are doing unnecessary IVFs and GIFTs because of the money spin-off (more costly procedure — more money made).
(The slimmer the indication, the better the success rates holds very true for GIFTs and IVFs).

IVF/GIFT SURVEY

CLINIC NAME: Michael Reese Hospital
ADDRESS: Dept OB GYN
Lake Shore Drive at 31st St
Chicago IL 60616

CONTACT PERSON: Edward L. Marut MD
PHONE NUMBER: 312-791-4000

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    - (a) Private ______
    - (b) Community hospital based X
    - (c) University based ______
    - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 7

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 7

6. How many other professionals participate in your clinic?
    - (a) Physicians 1
    - (b) Laboratory Scientists (PhDs) 2
    - (c) Nurses 4
    - (d) Embryo Lab Technicians/Technologists 2
    - (e) Other Lab Technicians/Technologists 2
    - (f) Radiology (Ultrasound) Technicians 1
    - (g) Psychologists/Counselors 1
    - (h) Secretaries 2
    - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 5½

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1987

9. How many different patients were stimulated?
1987 IVF 91 1988 IVF 99
GIFT 5 GIFT 56

10. How many stimulation cycles were performed?
1987 IVF 108 1988 IVF 128
GIFT 6 GIFT 56

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 109 1988 132

How many embryo transfer cycles were performed?
1987 97 1988 112

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 5 1988 56

13. What were the number and percentage of patients on IRB approved research protocols?
1987 91 100 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 57 62.6% 1988 IVF 51 51.5%
GIFT 0 0 % GIFT 2 3.6%
(b) Endometriosis:
1987 IVF 29 31.9% 1988 IVF 40 40.4 %
GIFT 5 100 % GIFT 29 51.8%
(c) Male infertility:
1987 IVF 18 19.8% 1988 IVF 27 27.3%
GIFT 3 60 % GIFT 27 48.2 %
(d) Unexplained Infertility:
1987 IVF 1 1 % 1988 IVF 2 3.6%
GIFT 0 0 % GIFT 14 25 %
(e) Other (explain): ovulatory, mixed etiologies
1987 IVF 10 11 % 1988 IVF 13 13.1%
GIFT 0 0 % GIFT 6 10.7%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 11 12.1% 1988 IVF 18 18.2%
GIFT 2 40 % GIFT 9 16.1%
(b) 31-35:
1987 IVF 45 49.5% 1988 IVF 48 48.5 %
GIFT 2 40 % GIFT 21 37.5%
(c) 36-40:
1987 IVF 31 34.1 % 1988 IVF 28 28.3 %
GIFT 1 20 % GIFT 20 35.7%

(d) 41-45:
1987 IVF 5 5.5% 1988 IVF 8 8.1%
GIFT 1 26% GIFT 5 8.9%

(e) >45:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 1 1.8%

16. How many clinical pregnancies were produced?
1987 IVF 9 1988 IVF 10
GIFT 1 GIFT 9

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 4 1988 IVF 1
GIFT 1 GIFT 4

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 5
GIFT 0 GIFT 4

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0%
GIFT 1 100% (Twins)

1988 IVF 0 0%
GIFT 1 25% (TWINS)

21. What are the qualifications of the director of the embryo laboratory? M.S. in gamete physiology

22. Who supervises the laboratory director? Ph.D. Director of Reproductive Biology

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 2
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 3
    (d) Nurses 0
    (e) Other (explain) 0

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. These comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Many patients have been rejected by other programs and are less than optimal candidates. We are more interested in providing an opportunity to these couples than preserving a success rate. Protocols used in early 1988 proved to be unsuccessful, and our current regimen has resulted in higher rate.

IVF/GIFT SURVEY

CLINIC NAME: Mount Sinai Hospital - Medical Center
ADDRESS: Department of Obstetrics & Gynecology
California Avenue at 15th Street
Chicago, Illinois 60608

CONTACT PERSON: Norbert Gleicher, M.D.
PHONE NUMBER: (312) 650-6727

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12-21-88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    (a) Private ______
    (b) Community hospital based ______
    (c) University based
    (d) Other (explain) University affiliated hospital

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? Two

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? Four

6. How many other professionals participate in your clinic?
    (a) Physicians Two
    (b) Laboratory Scientists (PhDs) one
    (c) Nurses four
    (d) Embryo Lab Technicians/Technologists one
    (e) Other Lab Technicians/Technologists Three
    (f) Radiology (Ultrasound) Technicians one
    (g) Psychologists/Counselors none
    (h) Secretaries three
    (i) Other (specify) Fellows - Two

7. How many years has your infertility clinic been in operation? Five years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT Jan/1986

9. How many different patients were stimulated?
1987 IVF 45 1988 IVF 62
GIFT 7 GIFT 2

10. How many stimulation cycles were performed?
1987 IVF 53 1988 IVF 72
GIFT 5 GIFT 2

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 34 1988 66

How many embryo transfer cycles were performed?
1987 32 1988 62

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 5 GIFT 1988 2 GIFT
2 GIFT/IVF 9 GIFT/IVF

13. What were the number and percentage of patients on IRB approved research protocols?
1987 51/51 100 % 1988 75/75 100 %

14. What were the number and percentage of patients treated for:

(a) Tubal factor:
1987 IVF 21/51 41.2 % 1988 IVF 33/59 55.9 %
GIFT ___ ___ % GIFT ___ ___ %

(50.0) 1/2 G/I
(20.0) 1/5 G
GIFT/IVF 1/13 (7.7)
GIFT 0/3 (0.0)

(b) Endometriosis:
1987 IVF 2/51 3.9 % 1988 IVF 0/59 0 %
GIFT ___ ___ % GIFT ___ ___ %

(0.0) 0/2 G/I
(20.0) 1/5 G
G/I 1/13 (7.7)
G 0/3 (0.0)

(c) Male infertility:
1987 IVF 7/51 13.7 % 1988 IVF 8/59 13.6 %
GIFT ___ ___ % GIFT ___ ___ %

(0.0) 0/2 G/I
(0.0) 0/5 G
G/I 3/13 (23.1)
G 1/3 (33.3)

(d) Unexplained infertility:
1987 IVF 4/51 7.8 % 1988 IVF 2/59 3.4 %
GIFT ___ ___ % GIFT ___ ___ %

(0.0) 0/2 G/I
(0.0) 0/5 G
G/I 1/13 (7.7)
G 0/3 (0.0)

(e) Other (explain): cervical, immunological
1987 IVF 17/51 33.3 % 1988 IVF 4/59 [illegible] %
GIFT ___ ___ % GIFT ___ ___ %

(50.0) 1/2 G/I
(60.0) 3/5 G
G/I 6/13 (46.2)
G 2/3 (66.7)

15. What were the number and percentage of patients in the following age groups:

(a) <31:
1987 IVF 11 21.6 % 1988 IVF 16 27.1 %
GIFT ___ ___ % GIFT ___ ___ %

(60.0) 3/5 G/I
(0.0) 0/2 G
G/I 1/13 (7.7)
G 1/3 (33.3)

(b) 31-35:
1987 IVF 20 39.2 % 1988 IVF 17 28.8 %
GIFT ___ ___ % GIFT ___ ___ %

(0.0) 0/5 G/I
(0.0) 0/2 G
G/I 8/13 (61.5)
G 1/3 (33.3)

(c) 36-40:
1987 IVF 20 39.2 % 1988 IVF 20 33.9 %
GIFT ___ ___ % GIFT ___ ___ %

(20.0) 1/5 G/I
(100.0) 2/2 G
G/I 2/13 (15.4)
G 1/3 (33.3)

(20.0) 1/5 G/I
(0.0) 0/2 C >

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 6 4.2 %
GIFT __ __ % GIFT __ __ %

< G/I 0/3 (0.0)
G 2/13 (15.4)

(0.0) 0/5 G/I
(0.0) 0/2 G >

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT __ __ % GIFT __ __ %

< G/I 0/3 (0.0)
G 0/13 0.0)

16. How many clinical pregnancies were produced?
1987 IVF 2 1988 IVF 17
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 1 1988 IVF 3
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 9
GIFT 0 GIFT __ < G/I 4
G 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 100 % No multiple births
GIFT 0 0 %

1988 IVF 3 100 % three sets of twins
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Reproductive Biology

22. Who supervises the laboratory director? Norbert Gleicher, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? Yes, CAP survey for
If the answer is yes, please specify which program.
radioimmunoassay — Amer. College of Pathologists

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Pending

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians Three
    (b) Laboratory scientists (PhDs) Two
    (c) Embryo laboratory technicians/technologists Four
    (d) Nurses Four
    (e) Other (explain) ____

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: In Vitro Fertilization Program

ADDRESS: Rush Presbyterian-St. Luke's Medical Center
1653 West Congress Parkway
Chicago, Illinois 60612

CONTACT PERSON: [+]Ewa Radwanska, MD, PhD/Richard G. Rawlins, PhD[*]
PHONE NUMBER: (312) 942-6609

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. **The following data is current through what date?** 11/17/88

2. **Does your clinic perform IVF/GIFT treatments?** Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. **What type of clinic do you operate? (Place X in appropriate space)**
   - **(a) Private** ____
   - **(b) Community hospital based** ____
   - **(c) University based** X
   - **(d) Other (explain)** ____

4. **How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic?** 3

5. **How many Board Certified Obstetricians/Gynecologists participate in your clinic?** 5(including 3 above + 2 Fellows)

6. **How many other professionals participate in your clinic?**
   - **(a) Physicians** 1 (resident)
   - **(b) Laboratory Scientists (PhDs)** 2
   - **(c) Nurses** 3
   - **(d) Embryo Lab Technicians/Technologists** ----
   - **(e) Other Lab Technicians/Technologists** RIA techs
   - **(f) Radiology (Ultrasound) Technicians** ----
   - **(g) Psychologists/Counselors** 1
   - **(h) Secretaries** 2
   - **(i) Other (specify)** Research Fellows, Scientists from Andrology and Biochemistry Labs.

7. **How many years has your infertility clinic been in operation?** 5

8. **When were the clinic's first IVF/GIFT stimulation cycles?**
IVF Nov. 1983 **GIFT** July 1987

[+] Program Director; [*] Laboratory Director

Note: 1988 Data reported through 11/17/88 only!

9. How many different patients were stimulated?
1987 IVF 46/31 1988 IVF 41/31 First trial/repeat cycle
GIFT 10/9 GIFT 48/28

10. How many stimulation cycles were performed?
1987 IVF 77 1988 IVF 72
GIFT 19 GIFT 76

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 77 1988 72

How many embryo transfer cycles were performed?
1987 62 1988 64

12. How many GIFT procedures (attempted egg recoveries) were performed? .
1987 19 1988 76

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 54 70 % 1988 IVF 50 69%
GIFT 3 16 % GIFT 13 17%
(b) Endometriosis:
1987 IVF 10 13 % 1988 IVF 7 10 %
GIFT 10 53 % GIFT 34 45 %
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 1 1 %
(d) Unexplained infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 1 5 % GIFT 0 0 %
(e) Other (explain): ovulatory dysfunction
1987 IVF 13 17 % 1988 IVF 15 21 %
GIFT 5 26% GIFT 28 37 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 15 19% 1988 IVF 21 31 %
GIFT 4 21 % GIFT 12 27 %
(b) 31-35:
1987 IVF 39 51% 1988 IVF 26 38%
GIFT 11 58 % GIFT 35 49 %
(c) 36-40:
1987 IVF 17 22 % 1988 IVF 18 26%
GIFT 4 27 % GIFT 16 23 %

(d) 41-45:
1987 IVF 4 5 % 1988 IVF 3 4 %
GIFT 0 0 % GIFT 8 11 %

(e) >45:
1987 IVF 2 3 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 12 1988 IVF 14
GIFT 8 GIFT 18

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 7 1988 IVF 2
GIFT 0 GIFT 7

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF n/a 1988 IVF 5
GIFT n/a GIFT 6
n/a (all delivered)

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 2

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 4 ___ % 3 twin, 1 triplet
GIFT 0 ___ % ___
1988 IVF 0 ___ % ___
GIFT 0 ___ % ___

21. What are the qualifications of the director of the embryo laboratory? PhD Zoology; Michigan State University - Endocrine

22. Who supervises the laboratory director? Director, Section of Reproductive Endocrinology and Infertility

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
External Institutional Review

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?

(a) Physicians 5
(b) Laboratory scientists (PhDs) 2
(c) Embryo laboratory technicians/technologists 3
(d) Nurses 2
(e) Other (explain) Visiting Research Fellows - 8

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The Rush IVF Program is university based and is associated with the Section of Reproductive Endocrinology Fellowship Program and a busy infertility practice. We provide comprehensive infertility evaluation and up to date treatment including assisted reproductive technology. IVF or GIFT are performed when indicated. Patients with less favorable prognosis (over 40 and with male factor) are not rejected. Three-hundred procedures have been performed with 70 pregnancies. Pregnancy rates per completed cycle have fluctuated between 18-26%.

IVF/GIFT SURVEY

CLINIC NAME: Evanston and Glenbrook Hospitals IVF Program
ADDRESS: 2050 Pfingsten Road
Suite 350
Glenview, IL 60025

CONTACT PERSON: John S. Rinehart, M.D., Ph.D.
PHONE NUMBER: 312-729-6450

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Sept 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1 (same as #4)

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 0
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 0
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? less than 2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1987 GIFT April 1988

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF 97
GIFT ______ GIFT ______

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF 110
GIFT ______ GIFT ______

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ________ 1988 100

How many embryo transfer cycles were performed?
1987 ________ 1988 90

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ________ 1988 10

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF 41 37%
GIFT ___ ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 23 21 %
GIFT ___ ___% GIFT 0 ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 30 28 %
GIFT ___ ___% GIFT 4 40 %
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF 16 14 %
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): as part of infertility evaluation
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT 6 60 %

15. What were the number and percentage of patients in the following age groups: Unknown
(a) <31:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF ____ 1988 IVF 29
GIFT ____ GIFT 4

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ____ 1988 IVF 5
GIFT ____ GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ____ 1988 IVF 15
GIFT ____ GIFT 3

19. How many ectopic pregnancies resulted?
1987 IVF ____ 1988 IVF 1
GIFT ____ GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___% ____________
GIFT ___ ___% ____________

1988 IVF 3 15% ____________
GIFT 3 100% ____________

21. What are the qualifications of the director of the embryo laboratory? Ph.D. with fellowships in andrology

22. Who supervises the laboratory director? No one

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: IVF ILLINOIS
ADDRESS: ILLINOIS MASONIC MEDICAL CENTER
836 W. WELLINGTON
CHICAGO, IL 60657

CONTACT PERSON: IRINA LIVSCHUTZ,R.N., NURSE COORD.
PHONE NUMBER: (312) 883-7096

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based ______
   - (d) Other (explain) PRIVATE, HOSPITAL BASED

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
   - (a) Physicians 1
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 5
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 2 YEARS

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF NOV. 1986 GIFT DEC . 1987

9. How many different patients were stimulated?
1987 IVF 47 1988 IVF 76
GIFT 18 GIFT 33

10. How many stimulation cycles were performed?
1987 IVF 86 1988 IVF 117
GIFT 21 GIFT 52

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 61 1988 90

How many embryo transfer cycles were performed?
1987 56 1988 79

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 15 1988 34

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0 % 1988 5 5 %
* MICRO-INJECTION OF SPERMATOZOA TO OOCYTE.

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 17 36% 1988 IVF 27 36%
GIFT 0 ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF 3 6% 1988 IVF 2 3%
GIFT 11 61 % GIFT 1 3 %
(c) Male infertility:
1987 IVF 14 30% 1988 IVF 11 14%
GIFT 3 17 % GIFT 4 12 %
(d) Unexplained infertility:
1987 IVF 1 2% 1988 IVF 1 1%
GIFT 1 6 % GIFT 7 21 %
(e) Other (explain): OVULATORY DYSFUNCTION
1987 IVF 12 26% 1988 IVF 35 46%
GIFT 3 17 % GIFT 21 64 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 2 4 % 1988 IVF 2 3 %
GIFT 0 ___% GIFT 5 15 %
(b) 31-35:
1987 IVF 21 45% 1988 IVF 28 37%
GIFT 8 44 % GIFT 9 27 %
(c) 36-40:
1987 IVF 18 38% 1988 IVF 32 42%
GIFT 8 44 % GIFT 16 48 %

(d) 41-45:
1987 IVF 6 13 % 1988 IVF 14 18 %
GIFT 2 11 % GIFT 3 9 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 5 1988 IVF 15
GIFT 0 GIFT 8

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 2 1988 IVF 4
GIFT 0 GIFT 6

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF - 1988 IVF 9
GIFT - GIFT 5

19. How many ectopic pregnancies resulted?
1987 IVF 1* 1988 IVF 0 *PATIENT-CONSERVATIVE
GIFT 0 GIFT 0 TREATMENT, SURGERY
WAS NOT REQUIRED

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 %
GIFT 0 0 %

1988 IVF 0 0 %
GIFT 3 50 % 3 SETS OF TWINS

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Genetics

22. Who supervises the laboratory director? MEDICAL DIRECTORS

23. Does the clinic participate in an external laboratory proficiency testing program? COLLEGE of AMERICAN PATHOLOGISTS
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? YES

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 5
    (b) Laboratory scientists (PhDs) 2
    (c) Embryo laboratory technicians/technologists 1
    (d) Nurses 1
    (e) Other (explain) ULTRASOUND TECHNICIAN - 1

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF Illinois, Inc. has been in operation since November 1986. We now offer all of the assisted reproductive technologies: In Vitro Fertilization-Embryo Transfer (IVF-ET), Gamete Intrafallopian Transfer (GIFT), and Zygote Intrafallopian Transfer (ZIFT). Our program complies with all of the recommendations of the American Fertility Society and is approved by the Society for Assisted Reproductive Technology. We submit our data to the IVF Registry.

IVF Illinois recently moved into a new 7,000 square foot facility dedicated to all of the assisted reproductive technologies. We are proud of the fact that our program provides not only quality medical service but also attends to the emotional needs of our patients. A member of our staff ia available to patients 24 hours a day in the event of an emergency.

We are presently developing several new and exciting programs: 1. Pre-implantion genetic diagnosis, 2. Microinjection of sperm into oocytes to enhance the possibility of fertilization in severe male factor infertility, and 3. Retrograde GIFT/ZIFT (non-surgical trans uterine placement of the tubal catheter). Preliminary results in these programs are very promising.

MICRO INJECTION OF SPERMATOZOA INTO THE PERIVITELLINE SPACE TO ENHANCE FERTILIZATION IN VITRO

INTRODUCTION

One of the indications for in vitro fertilization is male infertility. In some instances spermatozoa of an oligospermic male, or even a normospermic male are not capable of penetrating the zona pellucida of the oocyte. In this instance it is conceivable that micro-injection of a spermatozoa through the zona pellucida of the oocyte may result in fertilization.

MATERIAL AND METHODS - PATIENT SELECTION

The patient population is couples that have failed fertilization during a prior in vitro fertilization procedure or couples where the male has failed a sperm penetration assay. The couple will go through the regular in vitro fertilization protocol. Sperm will be prepared and a single sperm will be micro-injected into the perivitelline space under microscopic control. At the four to eight cell stage, the embryo will be transferred into the uterine cavity just as in the standard IVF protocol.

IVF PROGRAM

Patient Information

IVF
ILLINOIS
Reproductive
Genetics
Institute

In
Vitro
Fertilization
Program

IVF GLOSSARY

ASPIRATION	The suction removal of the egg (ovum or oocyte) from the ovary
CATHETER	A small hollow tube made of an inert, non-toxic material.
CLEAVAGE	Embryonic cell division
EMBRYO	A fertilized egg showing evidence of growth and cell division
ENDOMETRIOSIS	The presence of endometrial tissue (the normal uterine lining) in abnormal locations such as the tubes, ovaries, and peritoneal cavity.
FALLOPIAN TUBES	The pair of hollow structures attached to the uterus through which eggs pass from the ovaries
FERTILIZATION	The penetration of an egg by a sperm. Fertilization is the initial step of pregnancy and takes place in the fallopian tubes
FOLLICLE	Fluid-filled, cyst-like structure that develops in the ovary during each cycle and usually contains the egg
GAMETES	The sex cells—sperm and eggs—required for fertilization
IMPLANTATION	The embedding of the fertilized egg in the lining of the uterus
INSEMINATION	Exposure of eggs to sperm
LAPAROSCOPE	A slender, telescopic tube-like medical instrument
LAPAROSCOPY	The laparoscope is inserted through a small incision in the woman's abdomen (just below the "belly button"), to enable the surgeon to view the fallopian tubes, ovaries and uterus
OOCYTE	The unfertilized egg, also called the ovum
OVULATION	The spontaneous release of a mature egg from the ovary
ULTRASOUND	A painless technique using sound waves (sonar) to identify pelvic structures and measure follicle growth in the ovaries

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WHAT IS IVF?

In order for pregnancy to occur, an egg has to be released from the ovary and united with a sperm. Normally this union, called fertilization, occurs within the fallopian tube which joins the uterus to the ovary. However, in IVF the union occurs in a laboratory after egg and sperm have been collected. The embryo(s) is(are) then transferred to the uterus to continue growth.

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THE INEFFICIENCY OF HUMAN REPRODUCTION

Many people are surprised to realize that human reproduction is a relatively inefficient process. In a healthy couple, the probability of fertilization for any particular exposure of egg to sperm is approximately 80%, but by the time of the first expected menstrual period after ovulation, approximately one-half of the early embryos have already failed to develop. It is thought that many of these lost embryos were fundamentally abnormal and were incapable of survival. The menstrual period may not be delayed and the couple may not realize that an early pregnancy has been lost. If a menstrual period is missed, approximately one-fourth of the remaining embryos may still die later. The probability of a live birth after any one exposure in a normally fertile couple, therefore, is thought to be no higher than 30%.

Other studies have calculated the probability of pregnancy among population groups who do not use contraception. In clinical studies of this kind, the probability of a live birth after exposure in any one month is considered to be about 20%.

From a practical point of view, therefore, the expectancy of a continuing pregnancy which will result in the birth of a child after any one exposed cycle, in a normally fertile couple with one egg ovulated, is somewhere in the range of 20-30%.

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STEPS IN THE IVF PROCEDURE

1. Monitor the development of ripening egg(s) in the ovaries in response to medications.
2. Collect the eggs.
3. Obtain the sperm sample.
4. Put the egg(s) and sperm together in the laboratory and provide correct conditions for fertilization and early embryo growth.
5. Transfer the embryo(s) into the uterus.

To control the timing of egg maturation and to increase the chance of collecting more than one egg, fertility drugs selected for the woman's individual situation are prescribed. To check that egg development is satisfactory, vaginal ultrasound examinations of the ovaries are performed. Hormone levels are also checked by taking a series of blood and/or urine samples. Using this information, the physician determines if and when to administer an injection to cause final maturation of the eggs and when to schedule the egg retrieval.

The procedure to retrieve eggs is performed using a hollow needle guided by the ultrasound image (local anesthesia) or via laparoscopy (general anesthesia). Eggs are gently removed from the follicles by using the needle. This is called "follicular aspiration". Its timing is crucial because the egg will not develop properly if it is collected too early or too late.

Shortly after ultrasound-guided egg retrieval, or a few hours after laparoscopy, the patient may return home.

The eggs are immediately taken to an adjacent laboratory, where they are inseminated with sperm, obtained by masturbation and carefully washed and diluted. The sperm and eggs are then placed in an incubator to allow fertilization to take place. The eggs are examined carefully at intervals to determine if fertilization and cell division have taken place. If they have, the fertilized eggs are now called embryos.

Embryos that have developed satisfactorily are usually placed in the uterus on the second day following egg retrieval. An anesthetic is not required. A speculum is inserted into the vagina to expose the cervix. The embryos are drawn up into a catheter along with a few drops of fluid. They are then transferred into the uterine cavity. This procedure is painless. The transfer is followed by several hours of bedrest. At a later date, blood tests and possibly ultrasound examinations are performed to see if pregnancy has occurred.

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THE EXPECTED RATE OF SUCCESS WITH IN VITRO FERTILIZATION

It is unlikely that the rate of establishing a pregnancy from each egg by fertilization and development of in vitro followed by embryo transfer can improve on the rate of normal fertilization. Therefore, the maximum success per egg in any one cycle is likely to be in the 20-30% range. In the most experienced IVF programs, rates of pregnancy have usually been 10-20% per cycle. The ability to harvest more than one egg in most hormonally regulated cycles of IVF tends to offset some of the inefficiency of the in vitro process compared to nature. It may even occasionally result in the birth of twins, triplets, etc., if more than one transferred embryo grows in the uterus.

Despite the encouraging statistics, it must be emphasized that successful conception and childbirth for any specific couple *cannot be guaranteed* by any IVF program even if the couple undergoes multiple attempts. The probability of success depends on many factors including patient age, the cause of infertility, and the talent and experience of the IVF team. While almost all children resulting from human IVF have been normal, the possibility cannot be excluded that IVF could involve some unknown or increased risks to the children who are conceived by this method.

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CRITERIA FOR ACCEPTANCE INTO OUR IVF PROGRAM

1. IVF is of demonstrated value for patients with absence of both fallopian tubes or irreversible tubal blockage (where corrective surgery has either failed or is inadvisable). Couples with infertility related to lowered sperm counts or sperm motility may also be assisted, as may be those who have other causes of infertility such as endometriosis or who have unexplained infertility.
2. Only couples will be accepted.
3. There is no specific age limit for couples who may be considered for IVF in our program. However, success in women over forty years of age is low.

Please note that acceptance into the program and priority for initiation of therapy may depend on multiple additional factors.

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IVF FINANCIAL INFORMATION

The price of the procedure ranges from $4500-6000 depending on the medication protocol. Because there is no necessity for incurring hospital, anesthesia, or operating room charges, outpatient IVF performed entirely within the office using ultrasound-guided egg retrieval can be offered at a substantially lower cost to you than IVF with laparoscopic egg retrieval. Almost all our patients utilize and prefer the transvaginal ultrasound-guided egg retrieval. *Payment by check is requested at the time services are rendered.*

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IVF Illinois Reproductive Genetics Institute
An Affiliate of Illinois Masonic Medical Center
836 West Wellington Avenue Chicago, Illinois 60657 (312) 883-7096

GIFT PROGRAM

Patient Information

IVF
ILLINOIS
Reproductive
Genetics
Institute

Gamete
Intra-Fallopian
Transfer

GIFT GLOSSARY

ASPIRATION	The suction removal of the egg (ovum or oocyte) from the ovary
CATHETER	A small hollow tube made of an inert, non-toxic material
EMBRYO	A fertilized egg showing evidence of growth and cell division.
ENDOMETRIOSIS	The presence of endometrial tissue (the normal uterine lining) in abnormal locations such as the tubes, ovaries, and peritoneal cavity
FALLOPIAN TUBES	The pair of hollow structures attached to the uterus through which eggs pass from the ovaries
FERTILIZATION	The penetration of an egg by a sperm. Fertilization is the initial step of pregnancy and takes place in the fallopian tubes
FOLLICLE	Fluid-filled, cyst-like structure that develops in the ovary during each cycle and usually contains the egg
GAMETES	The sex cells–sperm and eggs–required for fertilization
IMPLANTATION	The embedding of the fertilized egg in the lining of the uterus
IN VITRO FERTILIZATION–EMBRYO TRANSFER (IVF-ET)	A procedure in which an egg is removed from a ripe follicle and fertilized by sperm outside the human body. The fertilized egg is allowed to divide in an incubator for about two days and then is inserted into the uterus of the woman
LAPAROSCOPE	A slender, telescopic tube-like medical instrument
LAPAROSCOPY	The laparoscope is inserted through a small incision in the woman's abdomen (just below the "belly button"), to enable the surgeon to view the fallopian tubes, ovaries and uterus
MINI-LAPAROTOMY	A small incision is made in the lower abdomen, approximately three inches long, just above the pubic hairline. This incision allows access to the tubes and ovaries. It is small enough so that patient discomfort is not great and the procedure can be performed on an outpatient basis
OOCYTE	The unfertilized egg, also called the ovum
OVULATION	The spontaneous release of a mature egg from the ovary
ULTRASOUND	A technique using sound waves (sonar) to identify pelvic structures and measure follicle growth in the ovaries
ZIFT	Zygote Intra-Fallopian Transfer
ZYGOTE	A fertilized egg

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WHAT IS GIFT?

GIFT is a new technique devised to achieve pregnancy in couples who have not been able to conceive using other treatments for infertility. The technique was developed in 1984.

The letters G-I-F-T stand for Gamete Intra-Fallopian Transfer. Essentially, the name explains the procedure. Gametes – the female's eggs and male's sperm – are placed into a catheter and then deposited directly into the woman's fallopian tubes. GIFT mimics the way a normally fertilized egg would begin its journey to the uterus for implantation.

A normal pregnancy begins with the release of an ovum (egg) from the woman's ovaries. The egg enters the fallopian tube where it meets with sperm that have traveled, following intercourse, from the vagina. The sperm fertilize the egg. The fertilized egg, now called an embryo, moves through the tube to the uterine cavity where it "floats" for another two days. The embryo then implants in the uterine wall approximately seven days after fertilization.

The GIFT technique follows nature by allowing the eggs to fertilize and develop in the natural environment of the fallopian tube, and then make their way to the uterus for implantation according to a normal timetable.

In contrast, "in vitro" fertilization (IVF) places fertilized eggs directly into the uterus ahead of schedule (before the embryo develops the same number of cells normally present when the embryo reaches the uterine cavity). Many researchers believe the relatively low success rate of IVF results because the IVF procedure places fertilized eggs directly into the uterus, ahead of schedule.

One of GIFT's major advantages is that the technique relies to a far greater degree on the body's natural processes and timetable to produce pregnancy.

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THE GIFT PROCEDURE

To prepare her body for the GIFT procedure, the woman receives hormones to stimulate development of multiple follicles. Administering hormones increases the chances of developing multiple follicles and of retrieving several mature eggs, each one capable of being fertilized.

The hormones are administered for about seven to 10 days. During this time, the patient is carefully monitored using laboratory tests and ultrasound scans. When tests show the eggs are mature and ovulation is about to occur, the patient is admitted for the GIFT procedure.

Egg retrieval is usually an office procedure requiring only the use of a local anesthetic and minimal intravenous sedation. Using vaginal ultrasound guidance, a thin needle is directed to each mature follicle and the fluid in it is aspirated. The egg, if present, is removed from the follicular fluid in the lab. Occasionally follicles are aspirated under direct vision at the time of a laparoscopy or mini-laparotomy.

Under ordinary circumstances, if at least four eggs are recovered at the time of aspiration, the patient is taken to the operating room. There, either with laparoscopy or mini-laparotomy, the end of each fallopian tube is grasped. A catheter containing two eggs plus sperm is placed into each tube and the eggs and sperm are deposited in the tube. (A new modification of GIFT holds the promise of eliminating the need for laparoscopy. This modified procedure called "retrograde GIFT" involves the passage of a very specialized system of catheters through the cervix into the uterus and then into the tube. This does not require any anesthetic and is essentially pain-free. Preliminary results with this procedure are promising.)

The transferred gametes come together in the fallopian tubes where the fertilization process can take place naturally. The resulting embryos are nurtured in the tubes, then move down into the uterus for implantation.

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WHO IS ELIGIBLE FOR GIFT?

Prerequisites for GIFT include normal fallopian tube(s), and a fertile male. Couples with infertility based on any of the following problems are good candidates for GIFT:

Unexplained infertility
Endometriosis
Immunological factors
Cervical factors

At present there are no age requirements for the GIFT procedure. Couples whose infertility results from a tubal factor are poor candidates for GIFT. These couples are better candidates for In Vitro Fertilization and Embryo Transfer (IVF-ET). Couples whose infertility results from a male factor are also poor candidates for GIFT. These couples are better candidates for In Vitro Fertilization or ZIFT.

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THE EXPECTED RATE OF SUCCESS WITH GIFT

Although GIFT is a relatively new technique, it offers considerable promise to couples who satisfy the criteria for eligibility. A large collaborative study reports that the clinical pregnancy rate for these couples is between 30% and 40%. There appears to be no significant increase in spontaneous abortion rates. There is, however, a slight increase in the incidence of tubal pregnancies and a significant increase in the incidence of multiple pregnancies with early studies suggesting that about 30% of all term pregnancies resulting from GIFT are twins. There is no increased incidence of birth defects with GIFT.

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GIFT FINANCIAL INFORMATION

We are sensitive to the high cost of GIFT and have designed our program to keep fees as low as possible. The price of the procedure ranges from $4500-6000 depending on the medication protocol. Maximal assistance with insurance reimbursement is also provided to all patients. Experience indicates that many patients will recover over 50% of their costs. *Payment by check is requested at the time services are rendered.*

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ZIFT PROGRAM

Patient Information

IVF
ILLINOIS
Reproductive
Genetics
Institute

Zygote
Intra-Fallopian
Transfer

ZIFT GLOSSARY

ASPIRATION	The suction removal of the egg (ovum or oocyte) from the ovary
CATHETER	A small hollow tube made of an inert, non-toxic material
EMBRYO	A fertilized egg showing evidence of growth and cell division
ENDOMETRIOSIS	The presence of endometrial tissue (the normal uterine lining) in abnormal locations such as the tubes, ovaries, and peritoneal cavity
FALLOPIAN TUBES	The pair of hollow structures attached to the uterus through which eggs pass from the ovaries
FERTILIZATION	The penetration of an egg by a sperm. Fertilization is the initial step of pregnancy and takes place in the fallopian tubes
FOLLICLE	Fluid-filled, cyst-like structure that develops in the ovary during each cycle and usually contains the egg
GAMETES	The sex cells—sperm and eggs—required for fertilization
GIFT	Gamete Intra-Fallopian Transfer
IMPLANTATION	The embedding of the fertilized egg in the lining of the uterus
INSEMINATION	Exposure of eggs to sperm
IN VITRO FERTILIZATION–EMBRYO TRANSFER (IVF-ET)	A procedure in which an egg is removed from a ripe follicle and fertilized by sperm outside the human body. The fertilized egg is allowed to divide in an incubator for about two days and then is inserted into the uterus of the woman
LAPAROSCOPE	A slender, telescopic tube-like medical instrument
LAPAROSCOPY	The laparoscope is inserted through a small incision in the woman's abdomen (just below the "belly button"), to enable the surgeon to view the fallopian tubes, ovaries and uterus
MINI-LAPAROTOMY	A small incision is made in the lower abdomen, approximately three inches long, just above the pubic hairline. This incision allows access to the tubes and ovaries. It is small enough so that patient discomfort is not great and the procedure can be performed on an outpatient basis
OOCYTE	The unfertilized egg, also called the ovum
OVULATION	The spontaneous release of a mature egg from the ovary
ULTRASOUND	A technique using sound waves (sonar) to identify pelvic structures and measure follicle growth in the ovaries
ZIFT	Zygote Intra-Fallopian Transfer
ZYGOTE	A fertilized egg

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WHAT IS ZIFT?

ZIFT is a technology available to infertile couples and is a modification of the GIFT procedure. ZIFT stands for Zygote Intra-Fallopian Transfer. Essentially the name explains the procedure. Zygotes (fertilized eggs in the very early stages of development) are placed in a catheter and injected directly into the woman's fallopian tubes during either a laparoscopy or a mini-laparotomy.

The technique is identical to the GIFT procedure up to and including egg retrieval. With ZIFT, the eggs are taken to the lab where they are exposed to sperm (inseminated). Fertilization is then allowed to take place in the lab as is the case for typical In Vitro Fertilization (IVF). Approximately 18 hours after insemination the eggs are examined. If fertilization takes place and healthy zygotes develop, the ZIFT procedure can be completed.

The woman is taken to the operating room where under general anesthesia, using either a laparoscopy or a mini-laparotomy, the zygotes are placed directly into the fallopian tubes.

At present, ZIFT is being performed for couples whose primary obstacle to pregnancy is a significant male factor. For these couples there is a question as to whether or not the sub-fertile semen has the ability to fertilize eggs. By using the laboratory for insemination there may be greater likelihood that fertilization will take place.

Transfer of the zygotes to the fallopian tubes within 24 hours of fertilization may be more physiological than transferring embryos into the uterine cavity approximately 48 hours after fertilization, as is the case with standard IVF.

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THE ZIFT PROCEDURE

To prepare her body for the ZIFT procedure, the woman receives hormones to stimulate development of multiple follicles. Administering hormones increases the chances of developing multiple follicles and of retrieving several mature eggs, each one capable of being fertilized.

The hormones are administered for about seven to 10 days. During this time, the patient is carefully monitored using laboratory tests and ultrasound scans. When tests show the eggs are mature and ovulation is about to occur, the patient is admitted for the ZIFT procedure.

Egg retrieval is usually an office procedure requiring only the use of a local anesthetic and minimal intravenous sedation. Using vaginal ultrasound guidance, a thin needle is directed to each mature follicle and the fluid in it is aspirated. The egg, if present, is removed from the follicular fluid in the lab. Occasionally follicles are aspirated under direct vision at the time of a laparoscopy or mini-laparotomy.

The eggs are immediately taken to an adjacent laboratory, where they are mixed with sperm, which have been obtained by masturbation and carefully washed and diluted. The sperm and eggs are then placed in an incubator to allow fertilization to take place. The eggs are examined carefully at intervals to ensure that fertilization and cell division have taken place. If they have, the fertilized eggs are now called zygotes.

On the day following aspiration, if zygotes have developed, the patient is taken to the operating room. There, either with laparoscopy or mini-laparotomy, the end of each fallopian tube is grasped. A catheter containing up to two zygotes is placed into each tube and the zygotes are deposited in the tubes. (A new modification of ZIFT holds the promise of eliminating the need for laparoscopy. This modified procedure called 'retrograde ZIFT' involves the passage of a very specialized system of catheters through the cervix into the uterus and then into the tube. This does not require any anesthetic and is essentially pain-free. Preliminary results with this procedure are promising.)

The zygotes are nurtured in the tubes and move down into the uterus where implantation takes place according to a normal timetable.

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WHO IS ELIGIBLE FOR ZIFT?

Prerequisites for ZIFT include normal fallopian tube(s). Couples with infertility based primarily on male factor problems are good candidates for ZIFT. At present there are no age requirements for the ZIFT procedure. Couples whose infertility results from a tubal factor are poor candidates for ZIFT. These couples are better candidates for In Vitro Fertilization and Embryo Transfer (IVF-ET).

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THE EXPECTED RATE OF SUCCESS WITH ZIFT

Although ZIFT is a relatively new technique, it offers considerable promise to couples who satisfy the criteria for eligibility. However, it is still too early to quote meaningful rates of success.

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ZIFT FINANCIAL INFORMATION

We are sensitive to the high cost of ZIFT and have designed our program to keep fees as low as possible. The price of the procedure ranges from $4500-6000 depending on the medication protocol. Maximal assistance with insurance reimbursement is also provided to all patients. Experience indicates that many patients will recover over 50% of their costs. *Payment by check is requested at the time services are rendered.*

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IVF Illinois Reproductive Genetics Institute
An Affiliate of Illinois Masonic Medical Center
836 West Wellington Avenue Chicago, Illinois 60657 (312) 883-7096

IVF/GIFT SURVEY

CLINIC NAME: The Center for Fertility and Reproductive Medicine
ADDRESS: Suite 665
1875 Dempster Street
Park Ridge, Illinois 60068

CONTACT PERSON: Charles E. Miller, M.D.
PHONE NUMBER: (312) 696 - 8217

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? March 1, 1989
2. Does your clinic perform IVF/GIFT treatments? Anticipate 10/1/89
(If the answer is no, there is no need to complete the remainder of the questionnaire.) Please see attached note.
3. What type of clinic do you operate? (Place X in appropriate space)
    (a) Private ________
    (b) Community hospital based ________
    (c) University based ________
    (d) Other (explain) ________
4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? ________
5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? ________
6. How many other professionals participate in your clinic?
    (a) Physicians ________
    (b) Laboratory Scientists (PhDs) ________
    (c) Nurses ________
    (d) Embryo Lab Technicians/Technologists ________
    (e) Other Lab Technicians/Technologists ________
    (f) Radiology (Ultrasound) Technicians ________
    (g) Psychologists/Counselors ________
    (h) Secretaries ________
    (i) Other (specify) ________
7. How many years has your infertility clinic been in operation? ________
8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF ________ GIFT ________

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF ______
GIFT ______ GIFT ______

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF ______
GIFT ______ GIFT ______

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ________ 1988 ________

How many embryo transfer cycles were performed?
1987 ________ 1988 ________

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ________ 1988 ________

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ____________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

19. How many ectopic pregnancies resulted?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ____________________
GIFT ___ ___% ____________________

1988 IVF ___ ___% ____________________
GIFT ___ ___% ____________________

21. What are the qualifications of the director of the embryo laboratory? ________________________________
____

22. Who supervises the laboratory director? ______________

23. Does the clinic participate in an external laboratory proficiency testing program? ______________
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? ______________

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? _____

26. Is the clinic a member of the Society for Assisted Reproductive Technology? ________________

27. Does the clinic train individuals in IVF or GIFT? ______
If the answer is yes, how many individuals in the following specialties have been trained?
    - (a) Physicians ________
    - (b) Laboratory scientists (PhDs) _______
    - (c) Embryo laboratory technicians/technologists _____
    - (d) Nurses _______
    - (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The Center for Fertility and Reproductive Medicine

The Lutheran General Medical Group, S.C.
Parkside Center 1875 Dempster St., Suite 665 Park Ridge, IL 60068 (312) 696-8217
Buffalo Grove Office 135 Arlington Heights Rd., Suite 150 Buffalo Grove, IL 60089 (312) 215-8890

Charles E. Miller, M.D.
Director

Laurence A. Jacobs, M.D.
Associate Director

March 9, 1989

Congressman Ronald Wyden
1406 Longworth House
Office Building
Washington, D.C. 20515

Dear Congressman Wyden:

I am sorry the response to your survey is so tardy in completion. Unfortunately, because our fertility program currently does not perform IVF/GIFT, I did not believe you were interested in our response.

We anticipate starting an IFV/GIFT Clinic through The Center for Fertility and Reproductive Medicine/Lutheran General Hospital, a community hospital based program in October of 1989. This will be a somewhat unique situation in that the clinic has a continuing consultation agreement with the Jones Institute Foundation of Norfolk, Virginia. The Jones Institute will provide initial training and continuing education for medical and administrative members of our clinic, oversee quality assurance in laboratories, provide current patient protocols, and will be instrumental in data collection.

If my office can provide any further information, please do not hesitate to contact me. Once again, I am sorry for any inconvenience my tardiness may have caused you or your office personnel.

Sincerely,

Charles E. Miller, M.D.

CEM:js

CC: D. Anne Murphy

We believe in Human Ecology, the understanding and care of human beings as whole persons in light of their relationships to God, themselves, their families and the society in which they live.

IVF/GIFT SURVEY

CLINIC NAME: Indiana University Medical Center
ADDRESS: Indiana University Hospital N 262
926 W. Michigan Street
Indianapolis, IN 46223

CONTACT PERSON: Marguerite E. Shepard, M.D.
PHONE NUMBER: (317) 274-4037

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/19/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based ______
   (c) University based X
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
   (a) Physicians 2
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 2
   (d) Embryo Lab Technicians/Technologists 2
   (e) Other Lab Technicians/Technologists 2
   (f) Radiology (Ultrasound) Technicians 3
   (g) Psychologists/Counselors 0
   (h) Secretaries 1
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 6.5

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 1983 GIFT 1987

9. How many different patients were stimulated?
1987 IVF 1 1988 IVF 3
GIFT 1 GIFT 31

10. How many stimulation cycles were performed?
1987 IVF 1 1988 IVF 3
GIFT 1 GIFT 37

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 0 1988 2

How many embryo transfer cycles were performed?
1987 0 1988 2

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 25

13. What were the number and percentage of patients on IRB approved research protocols?
1987 2 100% 1988 34 100%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 1 50 % 1988 IVF 3 9 %
GIFT ___ ___ % GIFT 9 26 %
(b) Endometriosis:
1987 IVF 1 50 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 8 24 %
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 11 32 %
(d) Unexplained infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 3 9 %
(e) Other (explain): ______________________
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 12 35 %
(b) 31-35:
1987 IVF 1 50 % 1988 IVF 2 6 %
GIFT 1 50 % GIFT 11 32 %
(c) 36-40:
1987 IVF 0 0 % 1988 IVF 1 3 %
GIFT 0 0 % GIFT 7 21 %

(d) 41-45:
1987 IVF 0 ___% 1988 IVF 0 0 %
GIFT 0 ___% GIFT 1 3 %

(e) >45:
1987 IVF 0 ___% 1988 IVF 0 0 %
GIFT 0 ___% GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF ___
GIFT 0 GIFT ___ 1 - IVF and GIFT combination

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF ___
GIFT ___ GIFT ___ 1 - IVF and GIFT combination

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF ___
GIFT ___ GIFT ___ Unknown

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___% ___
GIFT 0 ___% ___

1988 IVF 0 ___% ___
GIFT 0 ___% ___

21. What are the qualifications of the director of the embryo laboratory? Ph.D Biochemistry Post Doctoral Training in Andrology

22. Who supervises the laboratory director? Chief of Division of Reprodictive Endocrinology

23. Does the clinic participate in an external laboratory proficiency testing program? not formally
If the answer is yes, please specify which program.
However, the clinic adheres to guidelines established by the American Fertility Society, the American Andrology Society and the American Society of Tissue Ranks.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Ineligible until we have 3 term pregnancies

27. Does the clinic train individuals in IVF or GIFT? Not yet.
If the answer is yes, how many individuals in the following specialties have been trained?
(a) Physicians ________
(b) Laboratory scientists (PhDs) ________
(c) Embryo laboratory technicians/technologists ______
(d) Nurses ________
(e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Although the IVF program at Indiana University was initiated in 1983 it has not been in continuous operation since that time. After slightly more than a year of operation the majority of the staff left for more lucrative positions at a for-profit hospital in the same city. A second attempt to start a program met with the same fate.

The program as it is currently constituted was reinitiated in the Spring of 1987 with redevelopment of the Laboratory facilities. The first cases were scheduled to begin in January 1988. Two were scheduled in December 1987 because of insurance considerations.

GIFT services were added to IVF services with reinitiation of the program. Because of the emphasis on male factor infertility in our program, it was felt that IVF as a diagnostic procedure should be offered along with GIFT. We have no embryo freezing facilities and therefore had to transfer embryos when IVF was successful even if GIFT had been performed in the same cycle. Our thesis was that the transcervical embryo transfer should not interfere with transtubal transport of embryos if the transcervical transfer was performed carefully. Because many of the patients did not have insurance coverage for GIFT or IVF alone, many procedures were performed in conjunction with other procedures eg laser for endometriosis. In October 1988, three Reproductive Endocrinologists in private practice began doing their procedures in our hospital. All six of their cases have been GIFT procedures. All retrievals performed in 1988 were laparoscopic. The one cancelled IVF was intended to be ultrasound guided. Cancellation was because of inadequate stimulation. The two planned IVF only procedures were performed in conjuntion with a laparoscopy for evaluation of pelvic pathology (1-symptomatic hydrosalpinx, 1-assessment for possible sterilization reversal)

Of 37 intended GIFT/IVF or GIFT only cycles 10 were cancelled because of a premature LH serge. Two have had a subsequent treatment cycle with successful oocyte retrieval. The other 8 have yet to have a repeat treatment.

Comments
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All 7 patients intended for GIFT only had oocytes aspirated and transferred. Of 18 intended IVF/GIFT procedures 7 patients had both gametes transferred laparoscopically and embryos transferred transcervically, 5 had gametes transferred laparoscopically but no embryos transferred because of failure to fertilize, 5 had no gametes transferred laparoscopically but embryos transferred vaginally because of tubal disease and one because only immature oocytes were obtained. One patient had no gametes transferred because only immature oocytes were obtained and because these oocytes did not fertilize. She was the only patient who had neither gametes nor embryos transferred. The term pregnancy was from the combination gamete and embryo transfer group. Five patients are in the post retrieval but premenstrual phase of their cycle at the time of this report.

IVF/GIFT SURVEY

CLINIC NAME: Pregnancy Initiation Center
ADDRESS: Suite 110
8091 Township Line Rd.
Indianapolis, Indiana 46260

CONTACT PERSON: John C. Jarrett II M.D.
PHONE NUMBER: (317) 876-0539

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 10/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private X
   (b) Community hospital based ________
   (c) University based ________
   (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? Two

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? Three

6. How many other professionals participate in your clinic?
   (a) Physicians ________
   (b) Laboratory Scientists (PhDs) One
   (c) Nurses Five
   (d) Embryo Lab Technicians/Technologists Five
   (e) Other Lab Technicians/Technologists Three
   (f) Radiology (Ultrasound) Technicians ________
   (g) Psychologists/Counselors Four
   (h) Secretaries Three
   (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? Three

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 11/85 GIFT 1/86

9. How many different patients were stimulated?
1987 IVF 143 — 1988 IVF 153
GIFT 208 — Oct. GIFT 260
Combo 15 — Combo 22

10. How many stimulation cycles were performed?
1987 IVF 201 — 1988 IVF 210
GIFT 282 — Oct. GIFT 356
Combo 18 — Combo 34

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 152 — 1988 151 (Oct.)
How many embryo transfer cycles were performed?
1987 146 — 1988 145 (Oct.)

12. How many GIFT procedures (attempted egg recoveries) were performed? Through end of October
1987 192 — 1988 272
Combo 20 — Combo 42

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % — 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor: (undergoing surgery)
1987 IVF 59 49 % — 1988 IVF 85 67 %
Combo 1 5% GIFT 2 1 % — GIFT 3 1 % Combo 6 15%
(b) Endometriosis:
1987 IVF 22 18 % — 1988 IVF 15 12 %
Combo 8 40% GIFT 72 43 % — GIFT 80 36 % Combo 16 34%
(c) Male infertility:
1987 IVF 5 4 % — 1988 IVF 0 0 %
Combo 1 5% GIFT 31 19 % — GIFT 44 20 % Combo 9 22%
(d) Unexplained infertility:
1987 IVF 2 2 % — 1988 IVF 7 5 %
Combo 3 15% GIFT 44 26 % — GIFT 79 35 % Combo 5 12%
(e) Other (explain): Pelvic Adhesions
1987 IVF 33 27 % — 1988 IVF 18 14 %
Combo 7 35% GIFT 7 4 % — GIFT 12 5 % Combo 3 7%

	PCO 1987	PCO 1988
IVF	0 0%	0 0%
GIFT	7 4%	7 3%
Combo	0 0%	0 0%
	Other	Other
IVF	0 0%	1 0.8%
GIFT	3 2%	0 0%
Combo	0 0%	2 5%

15. What were the number and percentage of patients in the following age groups: (undergoing surgery)
(a) <31:
1987 IVF 30 28 % — 1988 IVF 39 33 %
Combo 7 39% GIFT 49 36 % — GIFT 88 37 % Combo 12 32%
(b) 31-35:
1987 IVF 52 49 % — 1988 IVF 58 49 %
Combo 8 44% GIFT 64 47 % — GIFT 102 43 % Combo 14 38%
(c) 36-40:
1987 IVF 21 20 % — 1988 IVF 20 17 %
Combo 3 17% GIFT 18 13 % — GIFT 37 16% Combo 11 30%

(d) 41-45:
1987 IVF 2 2% 1988 IVF 0 0%
GIFT 4 3% GIFT 9 4%

(e) >45:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 0 0%

16. How many clinical pregnancies were produced?
Surgery Date 1987 IVF 23 — 1988 Surgery Date IVF 17
GIFT 59 — GIFT 93
Combo 11 — Combo 12

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 12 — 1988 IVF 8
GIFT 20 — GIFT 53
Combo 1 — Combo 8

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 — 1988 IVF 11 (Scope date Feb 1 thru current Nov. 23)
GIFT 0 — GIFT 58
Combo 6

19. How many ectopic pregnancies resulted?
1987 IVF 1 — 1988 IVF 3
GIFT 8 — GIFT 9

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 8% twins - 1
GIFT 7 35% twins - 7
Combo 1 100% twins - 1
1988 IVF 1 12% triplets - 1
GIFT 21 40% twins - 16, triplets - 3, Quads - 1 Quints - 1
Combo 1 100% twins

21. What are the qualifications of the director of the embryo laboratory? See Attached

22. Who supervises the laboratory director? Physician and Ph.D.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians Ten
    (b) Laboratory scientists (PhDs) Two
    (c) Embryo laboratory technicians/technologists Twelve
    (d) Nurses Four
    (e) Other (explain) Three (administrators)

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Our program is private practice based and clinically oriented. While we do integrate new and worthwhile ideas into our protocols and procedures, little if any patient research is performed. We accept all couples regardless of age or disease process, but do carefully counsel all couples as to their chances of a successful pregnancy. Education and individual attention are stressed

IVF/GIFT SURVEY

CLINIC NAME: Center for Reproduction and Transplantation Immunology
ADDRESS: 1701 N. Senate Blvd
Indianapolis, IN 46202

CONTACT PERSON: Carolyn B Coulam, MD.
PHONE NUMBER: 317 929 5950

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/1/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    - (a) Private ______
    - (b) Community hospital based X
    - (c) University based ______
    - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
    - (a) Physicians 2
    - (b) Laboratory Scientists (PhDs) 2
    - (c) Nurses 2
    - (d) Embryo Lab Technicians/Technologists 4
    - (e) Other Lab Technicians/Technologists 0
    - (f) Radiology (Ultrasound) Technicians 1
    - (g) Psychologists/Counselors 0
    - (h) Secretaries 3
    - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 1 yr

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 8/87 GIFT 8/87

9. How many different patients were stimulated?
1987 IVF 12 1988 IVF 28
GIFT 4 GIFT 2

10. How many stimulation cycles were performed?
1987 IVF 22 1988 IVF 37
GIFT 6 GIFT 2

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 12 1988 35

How many embryo transfer cycles were performed?
1987 10 1988 30

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 6 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 10 83% 1988 IVF 12 43%
GIFT 0 0% GIFT 0 0%
(b) Endometriosis:
1987 IVF 0 0% 1988 IVF 6 21%
GIFT 1 25% GIFT 0 0%
(c) Male infertility:
1987 IVF 2 17% 1988 IVF 8 29%
GIFT 3 75% GIFT 0 0%
(d) Unexplained infertility:
1987 IVF 0 0% 1988 IVF 2 7%
GIFT 0 0% GIFT 0 0%
(e) Other (explain): Turner Mosaic/Prem. Ovar. Failure
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 2 100%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 7 58% 1988 IVF 11 39%
GIFT 1 25% GIFT 1 50%
(b) 31-35:
1987 IVF 4 33% 1988 IVF 13 46%
GIFT 1 25% GIFT 1 50%
(c) 36-40:
1987 IVF 1 8% 1988 IVF 4 15%
GIFT 2 50% GIFT 0 0%

(d) 41-45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

(e) >45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 6
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0 1989 expected
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 3
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0% ______________
GIFT 0 0% ______________

1988 IVF 0 0% ______________
GIFT 0 0% ______________

21. What are the qualifications of the director of the embryo laboratory? PhD in gamete physiology or previous experience in gamete handling

22. Who supervises the laboratory director? Medical Director

23. Does the clinic participate in an external laboratory proficiency testing program? yes
If the answer is yes, please specify which program.
SEOF cell exchange, ASHI/CAP Irasaki international cell + serum exchange, CLIA license.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? pending

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ______
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists 4
    (d) Nurses 2
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: University of Iowa Hospitals and Clinics
ADDRESS: Center for Advanced Reproductive Care
Iowa City, Iowa 52242

CONTACT PERSON: Craig H. Syrop, M.D.
PHONE NUMBER: 319/356/UIVF (356/8483)

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? November 30, 1988

2. Does your clinic perform IVF/GIFT treatments? YES
   (If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? Two

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? Three

6. How many other professionals participate in your clinic?
   - (a) Physicians three
   - (b) Laboratory Scientists (PhDs) One
   - (c) Nurses four
   - (d) Embryo Lab Technicians/Technologists Six
   - (e) Other Lab Technicians/Technologists Three
   - (f) Radiology (Ultrasound) Technicians None
   - (g) Psychologists/Counselors Three
   - (h) Secretaries Three
   - (i) Other (specify) Financial Advisor = One

7. How many years has your infertility clinic been in operation? 1-½ years

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF August 1987 GIFT August 1987

9. How many different patients were stimulated?
1987 IVF 16 1988 IVF 55
GIFT 4 GIFT 30

10. How many stimulation cycles were performed?
1987 IVF 22 1988 IVF 88
GIFT 5 GIFT 44

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 17 1988 62

How many embryo transfer cycles were performed?
1987 14 1988 59

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 4 1988 35

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 100 % 1988 ___ 100 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) ~~Male infertility~~:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ____________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

[illegible] IVF [illegible]

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 7 30 % 1988 IVF 23 29 %
GIFT 2 40 % GIFT 10 26 %
(b) 31-35:
1987 IVF 7 30 % 1988 IVF 32 41 %
GIFT 2 40 % GIFT 15 38 %
(c) 36-40:
1987 IVF 9 40 % 1988 IVF 20 25 %
GIFT 1 20 % GIFT 12 31 %

(d) 41-45:
1987 IVF 0 ___% 1988 IVF 4 5 %
GIFT 0 ___% GIFT 2 5 %

(e) >45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 11
GIFT 1 GIFT 10

Chemical Pregnancies
1987 IVF = 1
1988 GIFT = 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF 0
GIFT 0 GIFT 2

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 10
GIFT 0 GIFT 10

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___% ___
GIFT 0 ___% ___

Continuing Pregnancies
1988 IVF 0 ___% 50% singleton, 50% multiple gestations
GIFT 0 ___% 70% singleton, 30% multiple gestations

21. What are the qualifications of the director of the embryo laboratory? Masters & PhD with 10 years experience in Reproductive Physiology with domestic and laboratory animals.

22. Who supervises the laboratory director? Director of IVF Program

23. Does the clinic participate in an external laboratory proficiency testing program? YES
If the answer is yes, please specify which program.
Refer to attached document

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO, refer to attached document.

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? NO, see attached information

27. Does the clinic train individuals in IVF or GIFT? NO
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ____
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

SEE ATTACHED DOCUMENT.

Addendum to IVF/GIFT SURVEY

The following comments pertain to identified question numbers:

13. In agreement with proposals of minimum guidelines as set forth by the American Fertility Society, our entire programs is reviewed by our internal review board (The Human Subjects Review Board-Committee A/IRB-01). All patients' signed consents are approved by Committee A. As maintenance of a registry (IVF Registry) requires their approval, 100% of all of our patients are therefore on approved research protocols. Individual experimental protocols, although not currently being pursued, would require separate consents.

16. As regards number of clinical pregnancies produced, we use this term to infer ultrasound documented pregnancies. In the case of a blighted pregnancy or ectopic pregnancy, tissue diagnosis may accompany this.

17. Having only opened our program in late 1987, only 3 patients will have delivered by the time of this dictation.

21. Qualifications of the director of the embryo laboratory: Dr. Diane Hammitt possesses a Ph.D. in gamete biology and has had extensive prior experience in animal reproductive physiology.

23. This question has been addressed in a preceding letter to you. An external private corporation performs scheduled inspection visits.

24. Our Division has applied for but is not yet approved to provide a fellowship in reproductive endocrinology.

25. Our clinic meets or exceeds minimum guidelines set forth by the American Fertility Society.

26. This was addressed in a letter of explanation of our clinic. We are applying for membership in SART.

28. Please see preceding and accompanying letter.

As an addendum, our current stimulation protocol for patients pursuing in vitro fertilization - gamete intrafallopian transfer but not oocyte donors utilizes gonadotropin releasing hormone agonists (leuprolide acetate) to induce down regulation. This is followed by a protocol similar to that described by David Meldrum but utilizing Metrodin for the first 3 days of treatment. Since instituting this protocol, our cancellation rate has been markedly diminished (from approximately 30% to approximately 8-10%) and our pregnancy rate has improved dramatically.

Thank you.

Craig H. Syrop, M.D.
Assistant Professor

The University of Iowa
Iowa City, Iowa 52242

The University of Iowa Hospitals and Clinics
Department of Obstetrics and Gynecology

In Vitro Fertilization Scheduling
319/356-8483

December 13, 1988

The Honorable Ron Wyden
Suite 1406
Longworth House Office Building
Washington, D.C. 20515

Dear Representative Wyden:

I am in receipt of your letter of November 11, 1988 and regret that it has taken me so long to respond; however, I have been involved in pursuing subspeciality certification in reproductive endocrinology and infertility. Our In Vitro Fertilization - Gamete Intrafallopian Transfer Program at the University of Iowa is now approximately one year old. Although currently not eligible to become a voting member for the Society of Advanced Reproductive Technologies until more of our patients have delivered, we have been a voluntary member of the IVF Registry. Likewise, since our inception we have met or exceeded minimun guidelines set forth by the American Fertility Society and the American College of Obstetricians and Gynecologists. We have a multi-disciplinary team consisting of physicians, nurses, social workers, marriage and family counselors, an andrologist, a financial counselor, and perhaps most importantly an extremely well qualified Ph.D. gamete biologist. Furthermore, our IVF/GIFT Program represents a segment of a comprehensive program for infertility care. This program includes surgical services provided by myself and another (board certified) reproductive endocrinologist as well as an active donor insemination program utilizing only cryopreserved semen and an active ovulation induction program. Many patients referred to our in vitro fertilization or gamete intrafallopian transfer program are instead encouraged to pursue alternative therapy, including advice upon adoption by our social workers.

Embryo quality control for insemination services and the in vitro fertilization program have always been quite important to us. To this end, we maintain a separate embryo quality control lab representing an investment of over $150,000. Every piece of equipment and all media utilized in our program which may contact gametes is carefully tested by state of the art one- and two-cell mouse embryo culture techniques.

Likewise our water source is state of the art and has been tested by outside labs for purity and the presence of organic compounds. An outside independent corporation (Lab Safety Corporation of America) inspects and reviews our program on a regular basis with respect to the embryo lab's air and incubator quality. I have taken the liberty of enclosing an outline of our quality and embryo labs set up and quality control procedures. Actual forms or protocols are not included, but could be reviewed upon request. In turn, I request that our protocols for monitoring and quality control not be released for general circulation, but rather treated as confidential by A.F.S., S.A.R.T, or congressional members. It is important for you to realize that specific written laboratory protocols exist and are followed for preparation of all media, performance of all tests, and scheduling of routine inspection and testing of all equipment. Likewise, specific guidelines were utilized for the construction and air quality of our laboratory. I firmly believe that before instituting regulations regarding embryo laboratory functions that Ph.D.s actively involved in in vitro fertilization should be consulted. It is important to realize that protocols utilized successfully from one program may not be transferable to another program and that a specific given incubator temperature, C02 content or pH may not be strictly transferable. While absolute specific numbers may not be important, certainly guidelines apply. Like you and other members of the IVF registry, our program has been concerned with a failure of guideline enforcement. This extends not only as regards the actual performance of in vitro fertilization labs but extends as well to the qualifications and competence of those treating the patients.

While not related to the topic of in vitro fertilization, I would point out that likewise (unfortunately) no regulation exists regarding geographic location, number or acceptable success rates of transplant programs, or bypass surgery facilities. Furthermore, while the congressman is wisely concerned that there are neither publicly available nor uniform standards for reporting success rates with respect to IVF programs I would also note that no such records are available with regards to success of intensive care units, neurosurgeons, or trial lawyers. Surely, minimum patient numbers per year are related to success. I mention all of this only to say that this issue is not simple. Perhaps one of the most valuable services that could be offered by such legislation would be patient education or informed consent discussing important points to consider with respect to physician qualifications, services offered and clinic performance standards with specific reference to national standards.

However, recognize that if a program's existence is based solely upon their success rate, entire categories of patients with a reduced chance of success will not have access to care as clinics will fear lowering their success by inclusion of such patient groups. Finally, I indeed hope that you will press for support and funding of research in this area as such work could add immeasurably to subsequent treatment of infertile patients as well as that of genetically transmitted diseases.

Finally, in the past many patients have faced an undue burden being placed upon them when insurance companies have failed to recognize infertility treatments including gamete intrafallopian transfer and in vitro fertilization as viable alternatives, seeking to relegate this to "experimental" treatment. Speaking for our entire team, I hope that if we may be of further assistance in improving the care which infertile patients receive that you will feel free to contact us further.

Sincerely,

Craig Syrop

Craig H. Syrop, M.D.
Assistant Professor

CHS/dbb

THE UNIVERSITY OF KANSAS
College of Health Sciences
Bell Memorial Hospital
Kansas City, Kansas 66103

Department of Gynecology
and Obstetrics

William J. Cameron, M.D.
Professor

Kansas University Gynecological
and Obstetrical Foundation

February 8, 1989

Chairman Ron Wyden
B 363 Rayburn HOB
Washington, D.C. 20009
Attention: Mark Balkin

Re: IVF statistical questionnaire
mailed out November 1988

Dear Congressman Wyden:

We regret to inform your office that our In Vitro fertilization program has not been functional since September of 1988. The laboratory technician who was responsible for keeping such statistical data is no longer with us and the information you are requesting is not in any form suitable for reporting. It would take too much manpower and time to collect such data for you and we simply do not have that time or personnel available to us. We are sorry we cannot be of more assistance.

Sincerely,

WJCameron

William J. Cameron, M.D.
Professor
Department of Gynecology
and Obstetrics

WJC:ca

(913) 588-6246

New Pg 1&2 added 1/05/89

IVF/GIFT SURVEY

CLINIC NAME: The Center for Reproductive Medicine - [redacted] U of KS-Wichita

ADDRESS: 2903 East Central
Wichita, Kansas 67214

CONTACT PERSON: B.W. Webster, M.D.

PHONE NUMBER: 687-2112

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11-88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ____
   - (b) Community hospital based X
   - (c) University based X
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? As above

6. How many other professionals participate in your clinic?
   - (a) Physicians 2
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 4
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? 3.5 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 5-87 GIFT 1-87

9. How many different patients were stimulated?
1987 IVF 17 1988 IVF 18
GIFT 22 GIFT 21

10. How many stimulation cycles were performed?
1987 IVF 24 1988 IVF 22
GIFT 34 GIFT 25

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 16 1988 14

How many embryo transfer cycles were performed?
1987 13 1988 13

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 27 1988 20

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 16 67 % 1988 IVF 17 77%
GIFT 1 3 % GIFT 7 28 %
(b) Endometriosis:
1987 IVF 6 25 % 1988 IVF 4 18 %
GIFT 23 68 % GIFT 10 40 %
(c) Male infertility:
1987 IVF 2 8 % 1988 IVF 1 5 %
GIFT 3 9 % GIFT 5 20 %
(d) Unexplained infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 7 20 % GIFT 3 12 %
(e) Other (explain): ____________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 3 12 % 1988 IVF 4 18 %
GIFT 14 41 % GIFT 8 32 %
(b) 31-35:
1987 IVF 12 50 % 1988 IVF 12 55 %
GIFT 13 38 % GIFT 15 60 %
(c) 36-40:
1987 IVF 9 38 % 1988 IVF 6 27 %
GIFT 7 21 % GIFT 2 8 %

(d) 41-45:
1987 IVF __ __% 1988 IVF __ __%
GIFT __ __% GIFT __ __%

(e) >45:
1987 IVF __ __% 1988 IVF __ __%
GIFT __ __% GIFT __ __%

16. How many clinical pregnancies were produced?
1987 IVF 2 1988 IVF 5
GIFT 6 GIFT 3

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT 4 GIFT 2

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 5
GIFT 0 GIFT 2

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF __ __% ________
GIFT 0 __% ________

1988 IVF 0 __% ________
GIFT 1 50 % Twins

21. What are the qualifications of the director of the embryo laboratory? See attached.

22. Who supervises the laboratory director? B.W. Webster, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? Clinic lab - yes/IVF lab - no
If the answer is yes, please specify which program.
CAP, CLIA

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Application pending.

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

ADDENDUM

#21 The Director of the IVF/ET Laboratory holds a Ph.D. in biochemistry and received 4 years of postdoctoral training in Reproductive Endocrinology. He has 10 years experience in cell and tissue culture of ovarian cells and received 6 months training in IVF/ET techniques prior to assuming the Directorship of the IVF/ET Laboratory. He has directed the laboratory since January, 1988.

#22 The IVF/ET Laboratory Director answers directly to the Clinical Director of the IVF/ET Program. A team approach is taken with respect to the direction of the entire program.

IVF/GIFT SURVEY

CLINIC NAME: Reproductive Resource Center of Greater Kansas City
ADDRESS: 10600 Quivira, Suite 110
Overland Park, Kansas 66215

CONTACT PERSON: Rodney Lyles, M.D.
PHONE NUMBER: (913) 894-2323

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 10/3/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? None

6. How many other professionals participate in your clinic?
   - (a) Physicians None
   - (b) Laboratory Scientists (PhDs) None
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians None
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 3
   - (i) Other (specify) -

7. How many years has your infertility clinic been in operation? 2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 2/9/87 GIFT 12/2/86

9. How many different patients were stimulated?
1987 IVF 57 1988 IVF 67
GIFT 55 GIFT 59

10. How many stimulation cycles were performed?
1987 IVF 89 1988 IVF 121
GIFT 69 GIFT 94

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 68 1988 97

How many embryo transfer cycles were performed?
1987 66 1988 82

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 49 1988 70

13. What were the number and percentage of patients on IRB approved research protocols?
1987 -- --% 1988 -- --%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 29 32% 1988 IVF 65 53%
GIFT 16 23% GIFT 22 23%
(b) Endometriosis:
1987 IVF 36 41% 1988 IVF 15 12%
GIFT 30 43% GIFT 30 32%
(c) Male infertility:
1987 IVF 10 11% 1988 IVF 20 16%
GIFT 2 3% GIFT 17 18%
(d) Unexplained infertility:
1987 IVF 1 1% 1988 IVF 2 2%
GIFT 5 8% GIFT 14 15%
(e) Other (explain): Ovulation Dysfunction; Female Antisperm Antibodies
1987 IVF 13 15% 1988 IVF 19 16%
GIFT 16 23% GIFT 11 12%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 37 42% 1988 IVF 44 36%
GIFT 25 37% GIFT 29 31%
(b) 31-35:
1987 IVF 36 41% 1988 IVF 59 49%
GIFT 27 39% GIFT 50 54%
(c) 36-40:
1987 IVF 14 16% 1988 IVF 5 4%
GIFT 15 21% GIFT 12 13%

(d) 41-45:
1987 IVF 2 2 % 1988 IVF 13 11 %
GIFT 2 3 % GIFT 3 3 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 ___ %
GIFT 0 ___ % GIFT 0 ___ %

16. How many clinical pregnancies were produced?
1987 IVF 15 1988 IVF 13
GIFT 12 GIFT 31

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 1 1988 IVF 12
GIFT 3 GIFT 10

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 11
GIFT 0 GIFT 18

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 2

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___ % ___
GIFT 1 33 % Triplets = 1 set

1988 IVF 2 17 % Twins = 1 Triplets = 1
GIFT 5 50 % Twins = 3 Triplets = 1 Quads = 1

21. What are the qualifications of the director of the embryo laboratory? MS - Bacteriology/Immunology: M.T. (ASCP)

22. Who supervises the laboratory director? M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
C.A.P. for hormone assays

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** yes

27. **Does the clinic train individuals in IVF or GIFT?** No
If the answer is yes, how many individuals in the following specialties have been trained?
    - **(a) Physicians** ________
    - **(b) Laboratory scientists (PhDs)** _______
    - **(c) Embryo laboratory technicians/technologists** _____
    - **(d) Nurses** _______
    - **(e) Other (explain)** ________

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

Please note that the average length of infertility for both In Vitro Fertilization and GIFT patients was five years with an average patient age of 31.

Also note that in 1987 we performed 33 stimulation cycles in which women had a combination of GIFT/IVF. These did not fit in any of the previous categories and again consisted of 33 stimulations with 33 retrievals, 23 embryo transfers, 5 clinical pregnancies, 2 term deliveries, 1 twin gestation, 1 ectopic pregnancy, and 2 spontaneous abortions.

Rodney Lyles, M.D., Director
Reproductive Endocrinology

Reproductive Resource Center
OF GREATER KANSAS CITY

December 19, 1988

Ron Wyden, Chairman
Subcommittee on Regulation of Business Opportunities
Suite 1406
Longworth House Office Building
Washington, D.C. 20515

Dear Congressman Wyden:

You have recently received our "IVF/GIFT Survey" and I failed to include one aspect of the program that should have been inserted on the last page.

It is noted that our GIFT multiple gestation rate calculates to 50%; however, that is certainly not the ongoing multiple gestation rate with GIFT. Our ongoing (1988) pregnancies indicate a multiple gestation rate of 4 out of 18 clinical pregnancies for an overall percentage of 22%.

Thank you.

Sincerely,

R. Lyles

Rodney Lyles, M.D.

RL:pm

10600 Quivira Road • Suite 110 • Overland Park, Kansas 66215 • (913) 894-2323

IVF/GIFT SURVEY

CLINIC NAME: University of Kentucky
ADDRESS: University of Kentucky Medical Center, Dept. OB-GYN
800 Rose ST.
Lexington, Ky 40536

CONTACT PERSON: Ken Muse, M.D.
PHONE NUMBER: 606- 233 - 5410

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 1/1/89

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   - (a) Physicians ? 0 [Do Residents count?]
   - (b) Laboratory Scientists (PhDs) 4
   - (c) Nurses 2 +
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 2
   - (i) Other (specify) —

7. How many years has your infertility clinic been in operation? > 10

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF June 1985 GIFT MAY 1986

9. How many different patients were stimulated?
1987 IVF 33 1988 IVF ~~79~~56
GIFT 44 GIFT 14

10. How many stimulation cycles were performed?
1987 IVF 46 1988 IVF 79
GIFT 56 GIFT 19

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 26 1988 59

How many embryo transfer cycles were performed?
1987 24 1988 52

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 36 1988 14

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 14 42 % 1988 IVF 17 30 %
GIFT 1 2 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 6 18 % 1988 IVF 16 29 %
GIFT 19 41 % GIFT 5 36 %
(c) Male infertility:
1987 IVF 7 21 % 1988 IVF 12 21 %
GIFT 11 24 % GIFT 3 21 %
(d) Unexplained infertility:
1987 IVF 5 15 % 1988 IVF 9 16 %
GIFT 11 24 % GIFT 4 28 %
(e) Other (explain): MISC / mixed / DES
1987 IVF 1 3 % 1988 IVF 2 4 %
GIFT 4 9 % GIFT 2 14 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 3 9 % 1988 IVF 9 16 %
GIFT 9 20 % GIFT 2 14 %
(b) 31-35:
1987 IVF 14 42 % 1988 IVF 27 48 %
GIFT 17 37 % GIFT 7 50 %
(c) 36-40:
1987 IVF 13 39 % 1988 IVF 18 32 %
GIFT 14 [illegible] % GIFT 4 28 %
30

(d) 41-45:
1987 IVF 3 9 % 1988 IVF 2 4 %
GIFT 6 13 % GIFT 1 7 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 3 1988 IVF 9
GIFT 8 GIFT 3

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 2 1988 IVF 2
GIFT 5 GIFT 2

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 4
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 50 % 1 twin
GIFT 0 0 %

1988 IVF 0 0 % NONE
GIFT 2 14 % 1 twin, 1 triplet

21. What are the qualifications of the director of the embryo laboratory? Ph. D., Reproductive Biology

22. Who supervises the laboratory director? Division Head

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
CAP for RIA's

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? yes (?)

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 1 (Fellow)
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 0
    (d) Nurses 0
    (e) Other (explain) 0

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Infertility Program -
ADDRESS: Norton Hospital
200 E Chestnut Street
P.O. Box 35070
Louisville, Ky 40232-5070
CONTACT PERSON: Brenda Bissler RN / Dr Christine Cook
PHONE NUMBER: 502 562-8154

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Dec 1988

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    - (a) Private ______
    - (b) Community hospital based ✓
    - (c) University based ______
    - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
    - (a) Physicians 1
    - (b) Laboratory Scientists (PhDs) 1
    - (c) Nurses 1
    - (d) Embryo Lab Technicians/Technologists 1
    - (e) Other Lab Technicians/Technologists ______
    - (f) Radiology (Ultrasound) Technicians 5
    - (g) Psychologists/Counselors 0 (available on request)
    - (h) Secretaries 1
    - (i) Other (specify) 0

7. How many years has your infertility clinic been in operation? 1984

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1/8/84 GIFT Jan 1986

9. How many different patients were stimulated?
1987 IVF 44 1988 IVF 49
GIFT 1 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 57 1988 IVF 66
GIFT 1 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 49 1988 62

How many embryo transfer cycles were performed?
1987 43 1988 58

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 23 52 % 1988 IVF 29 59 %
GIFT 0 ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF 5 11 % 1988 IVF 6 12 %
GIFT 1 100 % GIFT 1 100 %
(c) Male infertility:
1987 IVF 13 30 % 1988 IVF 12 25 %
GIFT 0 ___% GIFT 0 ___%
(d) Unexplained infertility:
1987 IVF 3 7 % 1988 IVF 2 4 %
GIFT 0 ___% GIFT 0 ___%
(e) Other (explain):# of multiple diagnoses involved in a,b,c,d
1987 IVF 21 48 % 1988 IVF 20 41 %
GIFT 1 100 % GIFT 1 100 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 12 27 % 1988 IVF 9 18 %
GIFT 0 ___% GIFT 0 ___%
(b) 31-35:
1987 IVF 22 50 % 1988 IVF 23 27 %
GIFT 1 100 % GIFT 1 100 %
(c) 36-40:
1987 IVF 9 21 % 1988 IVF 13 27 %
GIFT 0 ___% GIFT 0 ___%

(d) 41-45:
1987 IVF 1 2 % 1988 IVF 4 8 %
GIFT 0 ___ % GIFT 0 ___ %
(e) >45:
1987 IVF 0 ___ % 1988 IVF 0 ___ %
GIFT 0 ___ % GIFT 0 ___ %

16. How many clinical pregnancies were produced?
1987 IVF 10 1988 IVF 13
GIFT 1 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 4 1988 IVF 8
GIFT 1 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 8 1988 IVF 9
GIFT 1 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 2 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 25 % 1 - triplet
GIFT 0 ___ %

1988 IVF 3 37 % 3 - twins
GIFT 0 ___ %

21. What are the qualifications of the director of the embryo laboratory? PhD molecular embryology, post-doctoral fellowship - UC Berkeley
IVF Training, John Muir Memorial Hospital - Walnut Creek CA.
AFS IVF Advanced Courses plus 2½ years hands on IVF experience.

22. Who supervises the laboratory director? Physician Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? no
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** Yes

27. **Does the clinic train individuals in IVF or GIFT?** Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) **Physicians** 3
    (b) **Laboratory scientists (PhDs)** ______
    (c) **Embryo laboratory technicians/technologists** ______
    (d) **Nurses** ______
    (e) **Other (explain)** ______

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

The Norton's In Vitro Fertilization program is part of a comprehensive infertility diagnostic and clinical treatment facility. Extensive infertility workup is afforded the patient before entrance into IVF. For this reason many infertility couples without tubal factor diagnosis are able to attain a pregnancy prior to the more complex and expensive IVF procedure.

For those remaining couples, many of whom have either a tubal factor and/or multiple other diagnosis, including a high rate of male factor problems, IVF is the first round choice of treatment with GIFT being the alternative for those of suitable indications and proven egg fertilization.

Even though our program accepts and works with couples diagnosed with a wide variety of infertility indicators, the "take-home" baby rate at our facility during 1987 and 1988, for those couples undergoing one or more IVF procedures (average is 2 per couple) is 18%.

IVF/GIFT SURVEY

CLINIC NAME: The Fertility Institute of New Orleans
ADDRESS: 6020 Bullard Avenue
New Orleans, Louisiana 70128
CONTACT PERSON: Richard P. Dickey, M.D., Ph.D.
PHONE NUMBER: (504) 246-8971

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/19/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private X
   (b) Community hospital based X
   (c) University based ____
   (d) Other (explain) ____

4. How many Board Certified Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
   (a) Physicians 1 urologist
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 6
   (d) Embryo Lab Technicians/Technologists 2
   (e) Other Lab Technicians/Technologists 4
   (f) Radiology (Ultrasound) Technicians 1
   (g) Psychologists/Counselors 1
   (h) Secretaries 3
   (i) Other (specify)
      Nursing Clerks 3
      Administrative Assistants 6
      Operating Room Technicians 1

7. How many years has your infertility clinic been in operation? 12

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1985

9. How many different patients were stimulated?
(*Some patients had both IVF and GIFT)

Prior to 1987		1987		1988		TOTAL	
IVF	424	IVF	131	IVF	62+4= 66	IVF	621
GIFT	55	GIFT	205	GIFT	172+7=179	GIFT	439
TOTAL	479	TOTAL	336	TOTAL	234 247	TOTAL	1060

10. How many stimulation cycles were performed?

Prior to 1987		1987		1988		TOTAL	
IVF	783	IVF	166	IVF	72+6= 78	IVF	1027
GIFT	97	GIFT	288	GIFT	222+7=229	GIFT	614
TOTAL	880	TOTAL	454	TOTAL	294 307	TOTAL	1641

11. For those clinics offering IVF:

How many egg recovery procedures were performed?

Prior to 1987 432 1987 98 1988 61+6=67 TOTAL 591+6=597

How many embryo transfer cycles were performed:
Prior to 1987 299 1987 81 1988 44+4=48 TOTAL 424+4=428

12. How many GIFT procedures (attempted egg recoveries) were performed?

Prior to 1987 56 1987 144 1988 156+7=163 TOTAL 356+7=363

13. What were the number and percentage of patients on IRB approved research protocols?

Prior to 1987 6 ____% 1987 0 0 % 1988 0 0 % TOTAL 6

14. What were the number and percentages of patients treated for:
NOTE: THESE TOTALS REFLECT ONLY DIAGNOSES FOR THE PATIENTS HAVING RETRIEVAL PROCEDURES PERFORMED. Primary diagnoses are shown with an additional category added for multiple factors*.

(a) Tubal factor:

Prior to 1987			1987			1988		
IVF	198	42.6%	IVF	53	60.1%	IVF	46	83.6%
GIFT	10	20.8%	GIFT	18	12.7%	GIFT	28	19.1%

(b) Endometriosis:

Prior to 1987			1987			1988		
IVF	159	35.8%	IVF	27	31.0%	IVF	0	0.0%
GIFT	26	54.2%	GIFT	71	50.0%	GIFT	63	42.8%

(c) Male Infertility:

Prior to 1987			1987			1988		
IVF	37	8.3%	IVF	5	5.7%	IVF	9	16.4%
GIFT	2	4.2%	GIFT	11	7.7%	GIFT	17	11.5%

(d) Unexplained Infertility:

Prior to 1987			1987			1988		
IVF	11	2.5%	IVF	2	2.3%	IVF	0	0.0%
GIFT	4	8.5%	GIFT	22	15.5%	GIFT	8	5.4%

(e) Other (explain): Ovulation Dysfunction

Prior to 1987			1987			1988		
IVF	48	10.8%	IVF	0	0.0%	IVF	0	0.0%
GIFT	6	12.8%	GIFT	20	14.1%	GIFT	31	18.4%

*(f) Other (explain): Multiple Factors

Prior to 1987			1987			1988		
IVF	152	34.2%	IVF	30	34.5%	IVF	15	27.3%
GIFT	30	63.8%	GIFT	58	40.8%	GIFT	68	44.8%

15. What were the number and percentage of patients in the following age groups?

(a) < 31:

	Prior to 1987		1987		1988		TOTAL	
IVF	181	40.6%	31	24.0%	17	30.9%	229	37.6%
GIFT	23	48.9%	58	40.8%	55	36.2%	136	40.4%

(b) 31-35:

	Prior to 1987		1987		1988		TOTAL	
IVF	198	42.4%	63	48.8%	24	43.6%	276	45.3%
GIFT	17	36.2%	55	39.7%	63	41.4%	129	40.0%

(c) 36-40:

	Prior to 1987		1987		1988		TOTAL	
IVF	59	13.2%	8	21.7%	13	23.6%	80	13.1%
GIFT	7	14.9%	24	16.9%	27	17.8%	54	16.0%

(d) 41-45:

	Prior to 1987		1987		1988		TOTAL	
IVF	16	3.6%	7	5.4%	1	1.8%	24	4.0%
GIFT	0	0.0%	5	3.5%	7	4.6%	12	3.6%

(e) > 45:

	Prior to 1987		1987		1988		TOTAL	
IVF	0	0.0%	0	0.0%	0	0.0%	0	0.0%
GIFT	0	0.0%	0	0.0%	0	0.0%	0	0.0%

16. How many clinical pregnancies were produced?
(LMPs in year indicated; includes ectopics and abortions with sacs [illegible]

	Prior to 1987	1987	1988	TOTAL
IVF	53	17	11	81
GIFT	17	40	59	116
TOTAL	70	57	70	197

17. How many women delivered live infants from IVF/GIFT?

	Prior to 1987	1987	1988	TOTAL
IVF	30	20	4	54
GIFT	1	26	36	63
TOTAL	31	46	40	117

18. How many women have continuing pregnancies from IVF/GIFT?

	1987	1988
IVF	0	10
GIFT	0	30

19. How many ectopic pregnancies resulted?

	Prior to 1987	1987	1988
IVF	1	3	2 (1 continuing w/triplets)
GIFT	0	2	1

20. What were the number, percentage of all births, and plurality, of multiple births?

Prior to 1987	IVF	5	17 %	4 twins, 1 triplet
	GIFT	0	0 %	
1987	IVF	7	35 %	5 twins, 2 triplets
	GIFT	8	31 %	7 twins, 1 triplet
1988	IVF	1	25 %	1 twin, 0 triplets
	GIFT	11	31 %	8 twins, 3 triplets

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in reproductive physiology; expertise in mammalian embryo culture, gamete physiology and cryobiology

22. Who supervises the laboratory director? Medical Director, M.D., Ph.D.

23. Does the clinic participate in an external laboratory proficiency testing program? yes
If the answer is yes, please specify which program.
College of American Pathologists (radioimmunoassay)

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No (All physicians are on the clinical staff of Louisiana State University Medical School or Tulane Medical School.)

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? yes (We are also one of nine regional centers participating in an NIH grant awarded to Medical Research International (the developers of The Registry for AFS)

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 12
    (b) Laboratory scientists (PhDs) 1
    (c) Embryo laboratory technicians/technologists 8
    (d) Nurses 10
    (e) Other (explain) ultrasound technicians - 7

28. Please provide any comments you may have on your clinic's patient population, treatments, or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

GIFT, instead of IVF, has been utilized in patients, since late 1987, except those with total tubal obstruction or with sperm counts less than 10 million per ml (normal is above 20 million per ml), due to the higher clinical pregnancy rate (41%) and birth rate (35%) per procedure with GIFT, compared to IVF (18% & 12%)[1] and to the diagnostic and therapeutic laser surgery advantages of laparoscopy.

Eggs not used at GIFT are fertilized in vitro and cryopreserved to establish a diagnosis in suspected husband factor problems and to increase pregnancy rates (1 birth from frozen embryos in 1988) or are donated to women without functioning ovaries.

References

1. Dickey RP, Taylor SN; Curole DN, Dunaway HD, Bordson BL: Comparison In Vitro Fertilization and Gamete Intrafallopian Transfer. 44th Annual Meeting of The American Fertility Society, Reno, Nevada, September, 1987, Abstract number P139

The Fertility Institute of New Orleans
A PROFESSIONAL CORPORATION

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TERRY T. OLAR, Ph.D.
Director, In Vitro Fertilization Laboratory
Member, American Fertility Society, Andrology Society

December 31, 1988

Representative Ron Wyden
Attention: Ms. D'Anne Murphy
363 Rayborn House Office Building
Washington, DC 20515

Dear Representative Wyden:

The purpose of this communication is fourfold. First, to update the report submitted to your office December 16, 1988 to coincide with the end of our IVF Clinic year in which the last procedure was completed December 16th rather than November 30th.

Second to correct the previous report by reclassifying some procedures from GIFT to IVF. These are the PROST procedures in which oocytes are fertilized in vitro before transfer into the fallopian tubes, to correct the number of ectopic pregnancies, and to remove pregnancies in which the quantitative was greater than 1000 miu/ml but a sac was not seen.

Third, to comment on the use of the term "clinical pregnancy". Following discussions with physicians at many IVF Centers about how they intended to respond to your questionnaire, I am concerned that clinical pregnancies will not be reported consistently, thereby, allowing some centers to report higher pregnancy rates than other equally or more successful clinics. At least three definitions of clinical pregnancy are in use: a) rising beta hCG of any amount more than 10 days post-retrieval, b) the presence of cytotrophoblastic cells on a D&C performed when no sac appears and c) the presence of a sac on ultrasound or else tissue evidence of an ectopic pregnancy. It is my understanding that only "C" is allowed by the Society of Reproductive Technology (SART). By using "B", as is done by IVF Australia among others, clinical pregnancy rates are inflated, but more importantly, patients are being subjected to unnecessary surgical procedures, since most obstetricians and gynecologists do not perform a D&C for early abortions in which a sac has not appeared, except to check for tubal pregnancy. If we counted patients who might have had cytotrophoblastic cells, if a D&C had been performed, rather than following the patients with laboratory testing, those with a beta hCG over 100 miu/ml, we would have had "additional" clinical pregnancies as follows: 6 GIFTs for 1987, and 1 IVF and 7 GIFTs for 1988. Since these differences in reporting clinical pregnancy might not have been fully understood by all respondents, I believe it would be fair and will serve to avoid criticism of your published report if either: 1) the category of "clinical" pregnancy is eliminated entirely in your published report or 2) all programs were allowed an opportunity to revise their report accordingly to the strictest criteria of equating clinical pregnancy with sacs and ectopics only.

Fourth, we wish to add the following statement to the explanation of our program. The clinical pregnancy rate for IVF in which 4 or more embryos were transferred in 1988 was 31.2% and the continuing or delivered pregnancy rate was 28.1%. Since 1983, the cumulative rates are 25.6% and 21.4%, respectively.

Sincerely,

Richard P. Dickey, MD, PhD

Richard P. Dickey, M.D., Ph.D.
Director, IVF and GIFT Program

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ABSTRACTS

SCIENTIFIC PAPERS TO BE PRESENTED
AT THE
FORTY-FOURTH ANNUAL MEETING OF
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OCTOBER 10–13, 1988
ATLANTA, GEORGIA

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The abstracts are those that will be presented in both oral and poster sessions and are published in the order of their presentation. Abstracts of special lectures and clinical seminars are not included.

The abstracts are printed exactly as submitted.

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In an effort to treat severe male infertility, human oocytes were inseminated in vitro after zona pellucida drilling (Gordon and Talansky, 1986), a micromanipulation technique whereby a hole is introduced into the zona pellucida which facilitates access of spermatozoa to the egg surface. Oocytes from 12 infertile couples were subjected to zona drilling and inseminated. In prior in vitro fertilization attempts, 0/76 oocytes recovered from these patients and inseminated without manipulation were fertilized. After zona pellucida drilling, 23/49 eggs fertilized, and of these 23, 11 were polyspermic (48%). Moreover, polyspermic eggs often contained more than 3, and occasionally as many as 7, pronuclei. Thus, despite the fact that the spermatozoa used for insemination were all from males with oligospermia and/or asthenospermia and teratospermia, the rate of polyspermy was high and the degree of polyspermy in multiply penetrated oocytes was marked. In zona-free oocytes of the mouse, where a block to polyspermy exists at the plasma membrane, such rates and degrees of polyspermy are rare. In the hamster, which blocks polyspermy effectively only at the level of the zona pellucida, zona-free inseminations result in a pattern of polyspermy similar to that observed in our human zona-drilled oocytes. Our data thus indicate that in the human, the oocyte blocks polyspermy at the zona pellucida, and that a block at the plasma membrane is either slow to develop or nonexistent.

054

Surgical Fertilization of Hamster Ova by Microinjection Induces the Zona Block to External Sperm Penetration. L. J. Burkman, A. Iritani, G. D. Hodgen, Dept. Ob/Gyn, Jones Institute for Reproductive Medicine, Eastern Virginia Medical School, Norfolk, VA.

We investigated the effect of surgical fertilization on the subsequent interaction of motile spermatozoa with the zona pellucida. In 10 experiments, one isolated head of a hamster sperm was microinjected into the ooplasm of ovulated hamster ova (n = 69). At 15–60 minutes postinjection, half of these eggs was challenged with capacitated hamster sperm (mTALP medium) to assess zona function. Control eggs (n = 230) and sham-injected eggs (n = 73) provided data on spontaneous activation, IVF rates, egg aging and the effects of mechanical damage and simple handling. Rapid degeneration occurred in 14% of all sperm-injected ova. Among the viable injected ova, 63.5% developed two pronuclei. An equivalent fraction (57%) of the sham ova was activated (1 pronucleus), but only 6% of non-inseminated control eggs activated. After 4 hours with motile sperm, the incidence of sperm penetration into the ooplasm was: 90% for fresh control ova, 27% for aged control ova (delayed insemination as with the micromanipulated eggs) and 0% ($p < 0.01$) for both the sperm-injected and sham groups. No sperm were found in the perivitelline space of micromanipulated eggs. All groups showed a low percentage of partial sperm penetration into the outer zona layer (3–17%). Furthermore, there were no significant differences for the mean number of sperm tightly bound to the zona, nor the percentage of bound sperm with a completed acrosome reaction (22–38%). We conclude that the punctured zona rapidly seals and that the microinjection procedure induces activation and a complete zona block to further sperm penetration, even when a sperm head is absent.

055

Pregnancy Rates in Cancelled Gamete Intrafallopian Transfer (GIFT) Cycles Treated With Intrauterine (IUI) or Cervical (CI) Insemination. R. P. Dickey, D. N. Curole, S. N. Taylor, P. H. Rye, T. T. Olar, The Fertility Institute of New Orleans, New Orleans, LA.

From April, 1986 to December, 1987, *312* cycles were initiated in patients with at least one patent tube and minimal semen criteria for GIFT. 151 GIFTs were performed with a pregnancy rate of 38%. 161 cycles were cancelled for premature LH surge (99) or poor follicular development (62). Cancelled patients were offered the option of IUI or CI and/or HCG 10,000 IU. The infertility diagnosis and results were:

	Endometriosis		Adhesions		Ovulation	
Treatment	pt	preg	pt	preg	pt	preg
No HCG or IUI	60	2	12	0	12	0
HCG no IUI	19	3	0	0	2	0
IUI/CI no HCG	5	1	0	0	0	0
HCG and IUI/CI	12	4	4	2	4	2

	Male		Unknown		Total		
Treatment	pt	preg	pt	preg	pt	preg	%Preg
No HCG or IUI	1	0	16	0	90	2	2%
HCG no IUI	0	0	3	0	24	3	12%
IUI/CI no HCG	7	2	2	0	14	3	21%
HCG and IUI/CI	11	3	5	2	33	11	33%

Pregnancy rates in patients who received HCG + IUI or CI (33%) were similar to rates in GIFT (38%) and significantly higher ($P < .001$) than rates in patients who chose HCG + coitus (12%) or coitus or coitus (2%). Pregnancy success was independently increased by IUI/CI ($P < .001$) and by HCG ($P < .001$). The results of IUI/CI combined with HCG in cancelled GIFT cycles should be compared to GIFT, transuterine tubal insemination (TUTI), pronuclear stage tubal transfer (PROST), zygote intrafallopian transfer (ZIFT) and intraperitoneal insemination (IPI), and IVF-ET in patients with patent fallopian tubes.

Family Planning in sexually active patients were sterilization (n = 14) or barrier methods (n = 3). With improved survival of FAR, attention should be focused in long term problems and reproduction.

P-210 *

Comparison of Gamete Intrafallopian Transfer (GIFT) and Intrauterine Insemination (IUI) for Treatment of Oligospermia. R. P. Dickey, D. N. Curole, S. N. Taylor, P. H. Rye, T. T. Olar, The Fertility Institute of New Orleans, New Orleans, LA.

During 1987, 130 GIFT procedures and 196 AIH-IUIs were performed with washed semen. IUI was timed with urine LH or US + hCG. Some IUI and all GIFT patients received clomiphene citrate (CC) and/or menotropin (M). Results:

Motile sperm/ml	AIH-IUI	Preg.	% Preg.	Gift	Preg.	% Preg.
≤2.0	13	0	0	2	0	0
2.1–4.0	8	0	0	4	2	50%
4.1–6.0	9	0	0	5	2	40%
6.1–8.0	8	0	0	4	2	50%
8.1–10.0	10	0	0	5	2	40%
10.1–20.0	32	3	9.4%	30	12	40%
20.1–30.0	38	4	10.5%	34	15	44.1%
30.1+	91	11	12.1%	46	20	43.5%

Pregnancy occurred in 8 of 20 GIFT (40%) and 0 of 48 IUI patients when initial counts were 2 to 10 × 10^6 motile sperm/ml ($P < .001$). The lowest counts associated with pregnancy were GIFT, 2.5 × 10^6 and IUI, 10.5 × 10^6 motile sperm per/ml during this study. We conclude that GIFT is an effective treatment for oligospermia when initial sperm counts are ≥2 × 10^6 motile sperm/ml.

P-211

Follicular Atresia Associated With Concurrent Initiation of a Gonadotropin Releasing Hormone Agonist (GnRH-a) and Follicle Stimulating Hormone (FSH) for Oocyte Recruitment for In Vitro Fertilization (IVF). R. G. Brzyski, S. J. Muasher, K. Droesch, S. Simonetti, G. S. Jones, Jones Institute for Reproductive Medicine, Norfolk, VA.

The ability of GnRH-a to cause an initial stimulation of serum gonadotropins was used for follicular recruitment for IVF in 12 infertile patients with a history of low estradiol (E_2) response to conventional gonadotropin stimulation. Stimulation was initiated on cycle day 3 with concurrent administration of leuprolide, 1 mg SQ/day, and FSH, 4 ampules IM/day. Leuprolide was discontinued on the day of hCG. Data are presented as means ± SEM. Basal serum LH and FSH levels on cycle day 3 were 15.6 ± 1.7 and 16.4 ± 2.2 mIU/ml, respectively. Serum LH and FSH increased to a peak of 124.3 ± 12.6 and 66.5 ± 3.9 mIU/ml, respectively, on cycle day 4, then gradually decreased to 30.8 ± 2.4 and 29.1 ± 1.8 mIU/ml, respectively, on the day of hCG. Serum progesterone levels increased from 0.97 ± 0.16 ng/ml on cycle day 3 to a peak of 3.01 ± 0.7 ng/ml on cycle day 6, then gradually decreased to 1.38 ± 0.46 ng/ml on the day prior to hCG. The mean day of hCG was 9.42 ± 0.3, and mean E_2 level on that day was 443 ± 43 pg/ml. One patient was cancelled for poor E_2 response, and one conceived with a current viable pregnancy. When results were compared with prior IVF attempts with only FSH stimulation in the same patients, significantly fewer preovulatory oocytes (1.75 ± 0.3 vs 2.75 ± 0.3) and more atretic oocytes (1.33 ± 0.5 vs 0.5 ± 0.2) were retrieved with the addition of GnRH-a than without it. It is concluded that concurrent initiation of leuprolide and FSH stimulation on cycle day 3 in patients with prior low response does not improve oocyte recruitment, and the high LH environment generated from initial stimulation of the agonist may be detrimental to normal oocyte development.

P-212

Pregnancy Outcome in Gamete Intrafallopian Transfer (GIFT) Cycles With Concurrent Good Embryo Quality and Cryopreservation. P. A. Schnarr, L. M. Broderick, M. W. Nessler, Pregnancy Initiation Center, Indianapolis, IN.

Previous studies have suggested increased pregnancy rates for patients undergoing In Vitro Fertilization when good embryo quality is observed. Further studies have correlated pregnancy following GIFT with blastocyst development of sibling eggs (Curole, et al., AFS Abstract #007, 1987). This study evaluates the correlation of these same parameters, embryo quality and progression to the blastocyst stage during a cryopreservation cycle, and the success of a concurrent GIFT cycle.

Since June 1986, 30 patients have undergone a GIFT cycle with coinciding embryo cryopreservation. Embryos were frozen at the 2–5 cell stage if they were deemed of excellent quality. All other embryos were observed and frozen only if they progressed to an expanded blastocyst. A total of 71 embryos were cryopreserved for these 30 patients. 22 of the 30 patients conceived as a result of the GIFT procedure. The pregnancy rate for this group was 73.3%. During this same period, 49 patients underwent GIFT, were cryopreservation candidates with at least one excess egg, but failed to have cryopreservation as a result of poor embryo quality and/or failure to progress in culture. 11 of the patients became pregnant following GIFT for a pregnancy rate of 22.4%. The difference in pregnancy rates for GIFT patients who received cryopreservation and for those whose embryos were not cryopreserved is significant (p less than .0001). These findings further suggest a positive correlation between embryo quality/progressive cleavage in culture and

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P-139 COMPARISON OF IN VITRO FERTILIZATION AND GAMETE INTRAFALLOPIAN TRANSFER. R. P. Dickey, S. N. Taylor, D. N. Curole, H. D. Dunaway, The Fertility Institute of New Orleans, B. L. Bordson, New Orleans, LA.

During 1986, 168 ovum retrievals (OR) for In Vitro Fertilization (IVF), 138 embryo transfers (ET); 44 ORs for Gamete Intrafallopian Transfer (GIFT), and eight combined GIFT and ETs were performed. Age, weight, method of stimulation, criteria for HCG administration and timing of OR were similar except the time lapse from HCG to OR was two hours longer for GIFT. Diagnoses were: Endometriosis: IVF 34%, GIFT 65%; Adhesions: IVF 43%, GIFT 4%; Ovulation defect: IVF 10%, GIFT 15%; Husband factors: IVF 3%, GIFT 11%; and Unknown: IVF 3%, GIFT 11%. There were 20 clinical IVF pregnancies, 12% per OR, 14% per ET, 14 clinical GIFT pregnancies, 30% per OR, and 2 GIFT plus ET, pregnancies, 25% per OR. The difference between pregnancy rates in GIFT and IVF per OR was significant, ($p = .002$). Three of nine patients who had both IVF and GIFT became pregnant, two with GIFT following failed IVF, and one with IVF following failed GIFT. There were five ectopic pregnancies, three following IVF, and two following GIFT. Excess GIFT eggs were inseminated and cultured as in IVF. In 31 of 46 GIFT patients with excess eggs, fertilization occurred. In 30, cleavage occurred and in 21 expanded blastocysts (EB) were obtained. When extra GIFT eggs developed to EB, 52% of patients became pregnant. When untransferred IVF embryos developed to EB, 40% of patients became pregnant. The difference was not significant. We conclude that GIFT should be used instead of IVF in patients who meet GIFT criteria of at least one normal tube, absence of significant antisperm antibodies, and minimal sperm standards and who have no contraindication to general anesthesia.

P-140 CUL-DE-SAC ARTIFICIAL INSEMINATION DETOUR(CULAID): PRELIMINARY REPORT OF EXPERIENCES WITH AN ALTERNATIVE TO GAMETE INTRAFALLOPIAN TRANSFER (GIFT) AND INTRATUBAL INSEMINATION. C. Nezhat*, W. Weiner*, N. Mitter**, D. Snoey**, C. P. Garrison**, *Center for Fertility and Endocrinology, Atlanta, GA; **IVF and Andrology Laboratory, West Paces Ferry Hospital, Atlanta, GA.

The objective of our study was to attempt to simplify the procedure for bringing capacitated sperm in contact with mature eggs, hopefully resulting in intrauterine pregnancy. We report an office procedure using stimulated ovarian cycles, washed and cultured sperm and artificial insemination through the cul-de-sac, 9 of 30 patients or 33%, who had been infertile for 2-14 years conceived in the first cycle.

Patients considered candidates for this treatment were couples with at least one patent fallopian tube and infertility assigned to one of the following categories: 1) cervical factor, 2) immune causes (sperm antibodies), 3) oligospermia, 4) idiopathic infertility, or 5) endometriosis unresponsive to conventional medical and surgical treatment. These patients were stimulated with Pergonal or Clomid as per a standard In Vitro protocol. The patients were followed by ultrasound and Estradiol levels. When the patient's follicles were felt to be mature, the patient was given 10,000 units of HCG IM. Thirty-four hours post HCG injection, .1-.2 ccs of the husband's washed sperm (prepared by standard IVF swim up technique) were injected into the cul-de-sac.

Based upon our results we believe CULAID is a simple and inexpensive office procedure for the successful treatment of some infertility patients.

P-141 PROGNOSTIC FACTORS FOR SUCCESSFUL ESTABLISHMENT OF PREGNANCY WITH GIFT. G. M. Grunert, L. J. Rodriguez-Rigau*, R. M. Woodward, E. C. Lotze, J. R. Feste, K. Smith*, E. Steinberger, *University of Texas Medical School, Baylor College of Medicine, Houston, TX.

Between February and December 1986, we performed 207 laparoscopically-directed GIFT procedures on 180 patients. The majority of procedures were done at second-look laparoscopy following either initial laparotomy or operative laparoscopy for pelvic factor infertility. The overall pregnancy rate was 20.3% per cycle (42 of 207), or 23.3% of patients (42 of 188). Simultaneous GIFT and IVF were performed in 24 cases with a similar success rate. There was significant decrease in pregnancy rate with male factor couples (8% pregnancy rate with less than 25 million total motile sperm) and in cycles with a single egg transfer. No improvement in pregnancy rate was observed when more than two eggs were transferred. Estradiol levels of below 600 pg/ml on the day of hCG administration were associated with a decreased chance of pregnancy. No difference was noted based on pelvic pathology, given that at least one normal, patent tube was present. Couples without male factor, with at least two mature eggs for transfer, and with an estradiol of greater than 600 pg/ml had a pregnancy rate of 32% per cycle.

ible total cessation of brain function. Death will have occurred at the time when the relevant functions ceased. In any case when organs are to be used in a transplant, then an additional physician, duly licensed in the state of Louisiana not a member of the transplant team, must make the pronouncement of death.

Added by Acts 1976, No. 233, § 1.

Cross References

Donation of organs, Uniform Anatomical Gift Act, see R.S. 17:2351 et seq.

Law Review Commentaries

Developments in the law, 1979-1980: Trusts and estates. Gerald LeVan, 41 La.L.Rev. 483 (1981).

Health and Malpractice—work of Louisiana Legislature for 1976 regular session. 37 La.L. Rev. 119 (1976).

Right to die: A current look. 30 Loyola L.Rev. (La.) 139 (1984).

CHAPTER 3. HUMAN EMBRYOS

Section
121. Human embryo; definition.
122. Uses of human embryo in vitro.
123. Capacity.
124. Legal status.
125. Separate entity.
126. Ownership.

Section
127. Responsibility.
128. Qualifications.
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130. Duties of donors.
131. Judicial standard.
132. Liability.
133. Inheritance rights.

§ 121. Human embryo; definition

A "human embryo" for the purposes of this Chapter is an in vitro fertilized human ovum, with certain rights granted by law, composed of one or more living human cells and human genetic material so unified and organized that it will develop in utero into an unborn child.

Added by Acts 1986, No. 964, § 1.

In this section as enacted in 1986, quotation marks were inserted around "human embryo" on authority of R.S. 24:253.

Title of Act:

An Act to enact Chapter 3 of Code Title I of Code Book I of Title 9 of the Louisiana Revised Statutes of 1950, to be comprised of R.S. 9:121 through 133, relative to in vitro fertilized ovum; to provide for the definition, capacity, legal status, ownership and the inheritance rights of human embryos; and to provide for related matters. Acts 1986, No. 964.

Law Review Commentaries

The legal status of the embryo. Lori B. Andrews, 32 Loyola (La.) L.Rev. 357 (1986).

Also ucd. Status of Embryo
32 Loy LR 317
by De Dicegy

§ 122. Uses of human embryo in vitro

The use of a human ovum fertilized in vitro is solely for the support and contribution of the complete development of human in utero implantation. No in vitro fertilized human ovum will be farmed or cultured solely for research purposes or any other purposes. The sale of a human ovum, fertilized human ovum, or human embryo is expressly prohibited.

Added by Acts 1986, No. 964, § 1.

§ 123. Capacity

An in vitro fertilized human ovum exists as a juridical person until such time as the in vitro fertilized ovum is implanted in the womb; or at any other time when rights attach to an unborn child in accordance with law.

Added by Acts 1986, No. 964, § 1.

Cross References

Unborn child, see C.C. art. 29.

§ 124. Legal status

As a juridical person, the in vitro fertilized human ovum shall be given an identification by the medical facility for use within the medical facility which entitles such ovum to sue or be sued. The confidentiality of the in vitro fertilization patient shall be maintained.

Added by Acts 1986, No. 964, § 1.

§ 125. Separate entity

An in vitro fertilized human ovum as a juridical person is recognized as a separate entity apart from the medical facility or clinic where it is housed or stored.

Added by Acts 1986, No. 964, § 1.

§ 126. Ownership

An in vitro fertilized human ovum is a biological human being which is not the property of the physician which acts as an agent of fertilization, or the facility which employs him or the donors of the sperm and ovum. If the in vitro fertilization patients express their identity, then their rights as parents as provided under the Louisiana Civil Code will be preserved. If the in vitro fertilization patients fail to express their identity, then the physician shall be deemed to be temporary guardian of the in vitro fertilized human ovum until adoptive implantation can occur. A court in the parish where the in vitro fertilized ovum is located may appoint a curator, upon motion of the in vitro fertilization patients, their heirs, or physicians who caused in vitro fertilization to be performed, to protect the in vitro fertilized human ovum's rights.

Added by Acts 1986, No. 964, § 1.

Cross References

Duties and rights of parents and children, see C.C. art. 215 et seq.

§ 127. Responsibility

Any physician or medical facility who causes in vitro fertilization of a human ovum in vitro will be directly responsible for the in vitro safekeeping of the fertilized ovum.

Added by Acts 1986, No. 964, § 1.

§ 128. Qualifications

Only medical facilities meeting the standards of the American Fertility Society and the American College of Obstetricians and Gynecologists and directed by a medical doctor licensed to practice medicine in this state and possessing specialized training and skill in in vitro fertilization also in conformity with the standards established by the American Fertility Society or the American College of Obstetricians and Gynecologists shall cause the in vitro fertilization of a human ovum to occur. No person shall engage in in vitro fertilization procedures unless qualified as provided in this Section.

Added by Acts 1986, No. 964, § 1.

§ 129. Destruction

A viable in vitro fertilized human ovum is a juridical person which shall not be intentionally destroyed by any natural or other juridical person or through the actions of any other such person. An in vitro fertilized human ovum that fails to develop further over a thirty-six hour period except when the embryo is in a state of cryopreservation, is considered non-viable and is not considered a juridicial[1] person.

Added by Acts 1986, No. 964, § 1.

[1] As appears in enrolled Act.

§ 130. Duties of donors

An in vitro fertilized human ovum is a juridical person which cannot be owned by the in vitro fertilization patients who owe it a high duty of care and prudent administration. If the in vitro fertilization patients renounce, by notarial act, their parental rights for in utero implantation, then the in vitro fertilized human ovum shall be available for adoptive implantation in accordance with written procedures of the facility where it is housed or stored. The in vitro fertilization patients may renounce their parental rights in favor of another married couple, but only if the other couple is willing and able to receive the in vitro fertilized ovum. No compensation shall be paid or received by either couple to renounce parental rights. Constructive fulfillment of the statutory provisions for adoption in this state shall occur when a married couple executes a notarial act of adoption of the in vitro fertilized ovum and birth occurs.

Added by Acts 1986, No. 964, § 1.

§ 131. Judicial standard

In disputes arising between any parties regarding the in vitro fertilized ovum, the judicial standard for resolving such disputes is to be in the best interest of the in vitro fertilized ovum.

Added by Acts 1986, No. 964, § 1.

§ 132. Liability

Strict liability or liability of any kind including actions relating to succession rights and inheritance shall not be applicable to any physician, hospital, in vitro fertilization clinic, or their agent who acts in good faith in the screening, collection, conservation, preparation, transfer, or cryopreservation of the human ovum fertilized in vitro for transfer to the human uterus. Any immunity granted by this Section is applicable only to an action brought on behalf of the in vitro fertilized human ovum as a juridical person.

Added by Acts 1986, No. 964, § 1.

§ 133. Inheritance rights

Inheritance rights will not flow to the in vitro fertilized ovum as a juridical person, unless the in vitro fertilized ovum develops into an unborn child that is born in a live birth, or at any other time when rights attach to an unborn child in accordance with law. As a juridical[1] person, the embryo or child born as a result of in vitro fertilization and in vitro fertilized ovum donation to another couple does not retain its inheritance rights from the in vitro fertilization patients.

Added by Acts 1986, No. 964, § 1.

[1] As appears in enrolled Act.

Cross References

Successions, capacity of unborn child, see C.C. art. 954.

CODE TITLE III—OF ABSENTEES

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2. Disposition of Unclaimed Specimens by Taxidermists 191

CHAPTER 1. UNIFORM DISPOSITION OF UNCLAIMED PROPERTY

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188. Power to make rules and regulations.

Acts 1978, No. 146, § 1 amended and reenacted Chapter 1 of Code Title III of Code Book I of Title 9 of the Louisiana Revised Statutes of 1950, formerly containing R.S. 9:151 to 9:156 (see main volume), to contain R.S. 9:151 to 9:188.

UNIFORM UNCLAIMED PROPERTY ACT (1981 ACT)

Tables of Jurisdictions Wherein Act Has Been Adopted

For text of Uniform Acts, and variation notes and annotation materials for adopting jurisdictions, see Uniform Laws Annotated, Master Edition, Volume 8A.

Jurisdiction	Statutory Citation
Alaska	AS 34.45.110 to 34.45.780.
Arizona	A.R.S. §§ 44-301 to 44-340.
Florida	West's F.S.A. §§ 717.001 to 717.1401.
Colorado	C.R.S. 38-13-101 to 38-13-134.
Hawaii	HRS §§ 523A-1 to 523A-41.
Idaho	I.C. §§ 14-501 to 14-542.
Iowa	I.C.A. §§ 556.1 to 556.29.
Louisiana	LSA-R.S. 9:151 to 9:188.
Maryland	Code, Commercial Law, §§ 17-101 to 17-326.
Minnesota	M.S.A. §§ 345.31 to 345.60.
Montana	MCA 70-9-101 to 70-9-316.
Nevada	N.R.S. 120A.010 to 120A.450.
New Hampshire	RSA 471-C:1 to 471-C:43.
North Dakota	NDCC 47-30.1-01 to 47-30.1-38.
Oregon	ORS 98.302 to 98.436.
Rhode Island	Gen.Laws 1956, §§ 33-21.1-1 to 33-21.1-41.
Tennessee	T.C.A. §§ 66-29-101 to 66-29-134.
Utah	U.C.A.1953, 78-44-1 to 78-44-40.
Vermont	27 V.S.A. §§ 1208 to 1238.
Virginia	Code 1950, §§ 55-210.1 to 55-210.30.
Washington	West's RCWA 63.29.010 to 63.29.905.
Wisconsin	W.S.A. 177.01 to 177.41.

THE FERTILITY INSTITUTE OF NEW ORLEANS

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Editorial Office
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To the editor:

The enclosed letter is submitted to Lancet because of your interest in this important topic. Four tables are included in order to provide verification of our statements. We hope that one or more might be used. The editors have the authors' permission to abbreviate tables or text as they find necessary.

Sincerely,

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To The Editor

Three, Four, or More

Sirs,

We have followed with interest the recommendations of Dr Ian Craft and colleagues (May 14, p. 1094), regarding the transfer of all oocytes at gamete intrafallopian transfer (GIFT), based on greater than 1000 GIFT procedures. We have re-analyzed Tables I and II of Dr Craft's data to determine the rate of continuing pregnancies by age group for each increase in number of oocytes transferred. We failed to find a significant increase ($p>.05$) in the number of women who continued pregnancy beyond the first trimester when more than 3 or 4 oocytes were transferred (Table I). Craft and colleagues (May 14, p. 1094) did not present oocyte numbers individually in their data, which prevented us from concluding whether it was preferable to transfer 3 versus 4 oocytes in order to reduce the level of multiparity.

Our own data, although consisting of fewer numbers, confirms Dr Craft and colleagues' findings that women under age 30 are at increased risk of giving birth to triplets, or higher order, when 4 or more oocytes are transferred. In our experience, triplet gestational sacs occurred in 16% of early pregnancies in women under age 30 and in 6% of those age 30 to 34, when 4 or more oocytes were transferred. However, triplets after age 34 occurred in only one patient who received 5 oocytes. Twin gestational sacs did not occur in women under age 30 when 2 oocytes were transferred, age 30-39 when 3 oocytes were transferred, or over age 40 when 4 or more oocytes were transferred. Four gestational sacs occurred in one patient with a poor fertility history, who received 7 oocytes, however, that pregnancy spontaneously reduced to 2 fetuses at 24 weeks.

Our clinical pregnancy rate is similar to that of Dr Craft and colleagues (Table II). We transfer only selected oocytes rather than all that are available. We utilize a stimulation regimen consisting of 150 IU human Menopausal Gonadotropin (hMG) daily for 7 or more days from the second cycle day, 150 IU of FSH for two days from the second cycle day and 100mg clomiphene citrate for 5 days from the second cycle day, which results in an average of 9.3 oocytes (7.7 mature) per retrieval. From these, we select 3 to 8 (average 4.3) mature oocytes for transfer. Excess oocytes are either fertilized in vitro, donated to other couples, or discarded. If fertilized in vitro, resultant sibling embryos are cryopreserved. When excess oocytes are fertilized in vitro and sibling embryos develop to the blastocyst stage prior to cryopreservation, the pregnancy rate is 78% (3).

Our experience does not support Dr Craft and colleagues contention that patients who produce multiple oocytes have a decreased chance of pregnancy and, therefore, require more oocytes be transferred. Rather, we have observed comparable continuing and multiple pregnancy rates when selected oocytes were transferred for patients in whom 4 to 22 oocytes were retrieved (Table III). Additionally, we have not observed a decrease in rate of continuing (34.3%) or multiple pregnancy (36.4% of continuing pregnancies) in patients with a diagnosis of polycystic ovaries (PCO).

Patients with previously demonstrated poor outcome of in vitro fertilized oocytes may require the transfer of a larger number of oocytes at subsequent GIFT procedures. Our patient who developed 4 early gestational sacs, that spontaneously reduced to 2 fetuses after transfer of 7 oocytes, had a previous failed GIFT procedure in which sibling oocytes fertilized, but developed into abnormal embryos in vitro.

Semen quality also may be a factor in overall GIFT success and in multiparity (Table IV). Like Craft and colleagues (November 5, p. 1087), we observed that when donor sperm were used for GIFT, pregnancy rates approached 50%. Furthermore, twins or higher order gestations occurred in 65% of patients under age 30 when donor sperm were used in the GIFT procedure.

We join Craft and colleagues in urging a flexible approach to determine the number of oocytes to transfer at GIFT. We propose that when twins are acceptable, the number of oocytes transferred be limited to 3 for ages < 30, 4 for ages 30-39, and that no limit be used for ages 40 and over. Exceptions may be made in cases of repeated abortion or a history of poor sibling embryo development in vitro. However, we caution that one failed GIFT cycle is not sufficient reason to transfer additional oocytes, unless there is concomitant evidence of poor in vitro development of sibling oocytes. In our experience, the pregnancy rate in second GIFT cycles (45.2%) is equal to the first attempt. It may be that other medical conditions, such as PCO, severe endometriosis, or severe pelvic inflammatory disease require greater numbers of oocytes be transferred, but this is yet unproven in our opinion. Finally, when donor sperm is used, the risk of multiple pregnancy is high, since this represents a more selected population of fertile individuals.

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3. Curole D, Dickey R, Taylor S, Olar T. Correlation of pregnancy after gamete intrafallopian transfer with fertilization and cleavage of sibling oocytes. Fertility & Sterility 1988; 50:811-12.

Table I

OUTCOME OF GIFT BY AGE GROUP AND NUMBERS OF OOCYTES TRANSFERED MODIFIED FROM CRAFT[1] TABLES I & II

#	Age Groups														
	< 30			30 - 34			35 - 39			40+			Overall		
Ocyt.	Pt/Prg	Ab	Cont*	Pt/Prg	Ab	Cont	Pt/Prg	Ab	Cont	Pt/Prg	Ab	Cont	Pt/Prg	Ab	Cont
1-2	13/3	0	3	27/7	1	6	36/4	1	3	39/2	0	2	115/16	2	14
(%)	23.1	0.0	23.0	25.9	14.3	22.2	11.1	25.0	8.3	5.1	0.0	5.1	13.9	12.5	12.2
3-4	35/9	2	7	69/25	9	16	102/21	2	19	57/10	5	5	263/65	18	47
(%)	25.7	22.2	20.0	36.2	36.0	23.2	20.6	9.5	18.6	17.5	50	8.7	24.7	27.7	17.9
5-6	46/20	5	15	102/44	7	37	107/38	10	28	55/16	9	7	310/118	31	87
(%)	43.5	25.0	21.7	43.1	15.9	36.3	35.5	26.3	26.2	29.1	56.2	12.7	38.1	26.3	28.1
7-8	36/17	1	16	93/39	7	32	89/42	12	30	25/6	3	3	243/104	23	81
%)	47.2	5.9	44.4	41.9	17.9	34.4	47.2	28.6	33.7	29.0	50.0	14.5	42.8	22.1	33.3
9-10	23/12	5	7	40/11	2	9	32/16	4	12	13/2	1	1	108/41	12	29
(%)	52.2	41.7	30.4	27.5	18.2	22.5	50.0	25.0	37.5	15.4	50.0	7.7	38.0	24.3	26.8
10+	6/3	2	1	12/7	0	7	10/5	2	3	4/1	0	1	32/16	4	12
(%)	50.0	66.7	16.7	58.3	0.0	58.3	50.0	40.0	30.0	25.0	0.0	25.0	50.0	25.0	37.5
TOTAL	154/64	15	49	343/133	26	107	376/126	31	95	193/37	18	19	107/360	90	270
(%)	40.2	23.4	30.8	38.8	19.5	31.2	33.5	24.6	25.3	19.2	48.6	9.8	33.6	25.0	25.2

[1] Craft I, Al-Shawaf T, Lewis PM, et al. Analysis of 1071 GIFT procedures: the case for a flexible approach to treatment. Lancet 1988; i:1094-98.

*Continuing Pregnancies

AND AGE GROUP
The Fertility Institute of New Orleans

Number of Oocytes	Age-Group					
	< 30					
	Patients	Clin Preg % Patients	Cont Preg % Patients	Twin % Cont*	Triplet % Cont	Quad %Cont
1-2	10	2 (20.0)	1 (10.0)	0	0	0
3	17	6 (35.3)	5 (29.4)	1 (20.0)	0	0
4	62	25 (40.3)	19 (30.6)	7 (36.8)	3 (15.8)	0
5	16	9 (56.2)	6 (37.5)	0	1 (16.7)	0
≥ 6	1	0	0	0	0	0
TOTAL	106	42 (39.6)	31 (29.2)	8 (25.8)	4 (12.9)	0

Number of Oocytes	30-34					
	Patients	Clin Preg % Patients	Cont Preg % Patients	Twin % Cont	Triplet % Cont	Quad %Cont
1-2	9	2 (22.2)	1 (11.1)	0	0	0
3	23	10 (43.5)	6 (26.1)	0	0	0
4	87	35 (40.2)	31 (35.6)	8 (25.4)	2 (6.4)	0
5	13	5 (38.5)	3 (23.0)	0	0	0
≥ 6	5	2 (40.0)	2 (40.0)	0	0	1(50)
TOTAL	137	54 (39.4)	43 (31.4)	8 (18.6)	2 (4.6	1(2.3)

Number of Oocytes	35-39					
	Patients	Clin Preg % Patients	Cont Preg % Patients	Twin % Cont	Triplet % Cont	Quad %Cont
1-2	1	0	0	0	0	0
3	11	3 (21.0)	0	0	0	0
4	35	15 (42.8)	13 (37.1)	3 (7.7)	0	0
5	10	6 (60.0)	4 (40.0)	1 (25.0)	1 (25.0)	0
≥ 6	3	0	0	0	0	0
TOTAL	63	24 (38.1)	17 (27.0)	4 (23.5)	1 (5.9)	0

Number of Oocytes	< 40					
	Patients	Clin Preg % Patients	Cont Preg % Patients	Twin % Cont	Triplet % Cont	Quad %Cont
1-2	2	0	0	0	0	0
3	7	0	0	0	0	0
4	9	3 (33.3)	1 (11.1)	0	0	0
5	0	0	0	0	0	0
≥ 6	1	0	0	0	0	0
TOTAL	19	3 (15.8)	1 (5.3)	0	0	0

Number of Oocytes	Overall					
	Patients	Clin Preg % Patients	Cont Preg % Patients	Twin % Cont	Triplet % Cont	Quad %Cont
1-2	22	4 (18.2)	2 (9.1)	0	0	0
3	58	19 (32.8)	11 (19.0)	1(9.1)	0	0
4	193	78 (40.4)	64 (33.2)	18(28.1)	5(7.8)	0
5	39	20 (51.3)	13 (33.3)	1(7.7)	2(15.4)	0
≥ 6	10	2 (20.0)	2 (20.0)	0	0	1(50)
TOTAL	322	113 (35.1)	82 (25.5)	20(24.3)	7(8.5)	1(1.2)

Table III OUTCOME OF GIFT BY NUMBER OF OOCYTES RETRIEVED
The Fertility Institute of New Orleans

Number	Number	Clinical Preg		Abortions		Continuing Preg		Number Sacs			
Eggs	Pts	Number	% Pts	Number	% Preg	Number	% Pts	1	2	3	4
1 - 2	9	2	22.2	0	0.0	2	22.2	2	0	0	0
3 - 4	35	11	31.4	2	18.2	9	25.7	8	1	0	0
5 - 6	45	17	37.8	6	35.3	11	22.2	8	2	1	0
7 - 8	36	25	44.6	3	12.0	20	35.7	12	5	3	0
9 - 10	59	19	32.2	4	21.0	14	23.7	10	4	0	0
11 - 12	38	16	42.1	5	31.2	10	26.3	6	3	1	0
13 - 14	28	11	39.3	3	27.3	8	28.6	6	2	0	0
15 - 16	19	6	31.6	1	16.7	5	26.3	3	1	1	0
17 - 18	10	4	40.0	1	25.0	3	30.0	2	0	1	0
19 - 20	7	4	57.1	2	50.0	2	28.6	2	0	0	0
21 - 22	6	2	33.3	0	0.0	2	33.3	2	0	0	0
>22	8	2	25.0	0	0.0	2	25.0	1	0	0	1
TOTAL	320	119	37.2	27*	22.7	88	27.5				

*4 Ectopics Not Shown

Table IV

SPERM COUNT AND OUTCOME OF GIFT
The Fertility Institute of New Orleans

Total Motile Sperm	Pts	Preg %Pts	Ab %Preg	Cont* %Pts	Gestations 1 %Cont	 2 %Cont	 3 %Cont	 4 %Cont
Age ≥ 35								
< 20x10^{6}	13	2 15.4	0 0.0	2 15.4	2 100.0	0 0.0	0 0.0	0 0.0
> 20x10^{6}	57	19 33.3	8 42.1	10 17.5	6 60.0	3 30.0	1 10.0	0 0.0
Donor	11	6 54.5	1 16.7	5 45.4	4 80.0	1 20.0	0 0.0	0 0.0
Age < 35								
< 20x10^{6}	33	8 21.7	0 0.0	8 21.7	6 60.0	1 10.0	1 10.0	0 0.0
> 20x10^{6}	161	62 38.5	14 22.6	45 28.0	32 71.1	11 24.4	2 6.2	0 0.0
Donor	45	23 51.1	4 17.4	18 40.0	10 35.5	5 27.8	2 11.1	1 5.6

*Continuing Pregnancies

LOYOLA
LAW REVIEW

The Medical Status of the Embryo

Richard P. Dickey, M.D., Ph.D.

ARTICLES

THE MEDICAL STATUS OF THE EMBRYO

*Richard P. Dickey, M.D., Ph.D.**

The birth of Louise Brown, the first baby to be conceived by *in vitro* fertilization (IVF), on July 25, 1978, was a landmark event in human history.[1] The medical, legal, and moral implications of this event are still new and not completely resolved. To the physician specializing in the treatment of infertility, the birth of Louise Brown was the answer to a problem of increasing concern over the past twenty-five years. That problem is and continues to be the rising incidence of infertility in women who have postponed childbearing for ten to twenty years beyond the customary time for the birth of a first child.[2] That time historically had been one to two years after the onset of sexual maturity as indicated by the first menstrual period. In the United States and Europe, the time had been extended during the past century to the age of eighteen to twenty as women became educated and worked outside their parents' home. In many ways, this problem coincides with the modern era of new technologies in contraception which began with the introduction of the birth control pill in 1960[3] and with the introduction of the modern intrauterine device in 1962.[4] The postponement of pregnancy past the age of eighteen to twenty in the majority of women in the United States, however, dates back not much more than five decades and has as its causes, in addition to the availability of contraception and the increased educational and work status of women, the occurrence of World War II and the Great Depression.[5]

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[1] Edwards, *Test-Tube Babies*, 293 NATURE 253, 253-56 (1981).

[2] Population Information Program, The Johns Hopkins University, *Age at Marriage and Fertility*, 7 POPULATION REP. M-105 (1979); *see also* Population Information Program, The Johns Hopkins University, *The Impact of Family Planning Programs on Fertility*, 13 POPULATION REP. J-733 (1985); Population Information Program, The Johns Hopkins University, *After Contraception: Dispelling Rumors About Later Childbearing*, 12 POPULATION REP. J-697 (1984).

[3] Pincus, *Clinical Effects of New Progestational Compounds*, CLINICAL ENDOCRINOLOGY 526-31 (E. Astwood ed. 1969).

[4] *See* H. TATUM & E. CONNELL, MANAGING PATIENTS WITH INTRAUTERINE DEVICES 8

I. INCIDENCES AND CAUSES OF INFERTILITY

In 1982, more than one in eight couples were classified as infertile; that is, they had not used contraception and had failed to conceive for at least one year.[6] Nearly one in five married women of reproductive age reported that they had sought professional consultation at some time during their life because of the inability to have children.[7] The incidence of infertility is particularly high among women thirty-five years of age and older. The incidence for women doubles between the ages of twenty-five to twenty-nine and thirty to thirty-four years and then doubles again for ages thirty-five to thirty-nine.[8] Peak fertility for women occurs during the teen years, beginning one to two years after the first menstrual period.

The most frequent cause of infertility in women who seek *in vitro* fertilization is tubal disease resulting from infection, endometriosis, or a previous therapeutic or elective surgery.[9] These conditions are nearly all acquired after the onset of the first fertile cycles at age thirteen to sixteen. In addition, women seeking IVF are

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(1985). "Margules, in 1962, developed the first plastic IUD . . . . Lippes, in 1965, developed . . . . the first widely studied plastic loop bearing a monofilament plastic tail . . . ." *Id.* at 6.

[5] *See* Pincus, *supra* note 3.

[6] Centers for Disease Control, *Infertility—United States, 1982,* 34 Morbidity & Mortality Weekly Rep. 197, 197.

[7] *Id.*

[8] *Id.* at 198.

[9] H.W. Jones and others reported the primary diagnosis in 560 cycles in 319 IVF patients as follows: tubal disease 81.1%, male factors 5.4%, diethylstibestrol exposure 4.5%, endometriosis 3.6%, no cause found 3.5%, and miscellaneous 2.3%. Jones, Acosta, Andrews, Garcia, Jones, Mayer, McDowell, Rosenwaks, Sandow, Veeck & Wilkes, *Three Years of In Vitro Fertilization at Norfolk*, 42 Fertility & Sterility 826, 829 (1984) [hereinafter Jones].

Wood and others in Melbourne, Australia, reported a primary diagnosis in 1533 cycles in 831 patients as: tubal disease 36.7%, uncertain 31.2%, male factor 14.3%, endometriosis 3.5%, and miscellaneous 14.3%. Wood, McMaster, Rennie, Trounson & Leeton, *Factors Influencing Pregnancy Rates Following In Vitro Fertilization and Embryo Transfer*, 43 Fertility & Sterility 245-50 (1985) [hereinafter Wood].

See also Lopata, Johnston, Leeton & McBain, *Use of In Vitro Fertilization in the Infertile Couple*, in The Infertile Couple 209 (1980).

often older than the average woman who seeks infertility treatment and therefore more likely to have anovulatory cycles.[10] *In vitro* fertilization is also used for treatment of men with very low sperm counts who cannot achieve pregnancy with their wives by use of their own sperm by any other method.[11] In men, the causes are also most frequently acquired conditions. Chronic infections of the urinary system or prostate gland and injury or a vascular condition of the testicles which has occurred after the onset of male sexual maturity are the most common causes of male infertility.[12] These couples, now married and infertile, were at one time individually and together fertile. Through no fault of their own, except the delay in attempting a family, they have become infertile and candidates for *in vitro* fertilization.

II. THE INEFFICIENT NORMAL HUMAN REPRODUCTIVE CYCLE

The normal human reproductive cycle is enormously wasteful of human eggs and human sperm. A woman is born with all the eggs she will ever have, estimated to be about 2,000,000.[13] By puberty this number has been decreased to 400,000-500,000,[14] a loss of 80%. Beginning with the first menstrual cycle at age thirteen to sixteen, 1,000 eggs begin to develop in the ovaries each month. Only one egg usually reaches full maturity, while the remainder eventually stop growing and degenerate *in situ*. On the average, a woman has approximately 400 ovulatory cycles during her lifetime.[15] Thus only 400 eggs ever have the opportunity of being fertilized and developing into an embryo. However, during pregnancy and while a baby is being nursed, all the eggs which begin to develop stop growing and degenerate *in situ*.[16] If we assume that a woman may become pregnant on the average of once every two years, that she nurses her newborn, and that the first birth occurs at age 15, and the final birth around age 45,[17] then it would be possible for sixteen term pregnancies to occur during a woman's lifetime.[18] This number is well within many historical precedents. Thus, without birth control, only sixteen out of 400,000 eggs usually reach maturity, are fertilized by sperm, develop into embryos, enter the uterus, implant, and survive to become a full term newborn infant.

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[10] *See* Centers for Disease Control, *supra* note 6, at 198; Jones, *supra* note 9, at 829; Woods, *supra* note 9, at 247.

[11] *See* Jones, *supra* note 9.

[12] *See* LaNasa & Urry, *Evaluation and Treatment of the Infertile Male*, 3 SEMINARS IN REPRODUCTIVE ENDOCRINOLOGY 113 (1985).

[13] *See* J. PRITCHARD & P. MACDONALD, WILLIAMS OBSTETRICS 97 (16th ed. 1980).

[14] *Id.*

[15] Based on an estimation that the average age woman will have 13 menstrual cycles yearly from age thirteen to forty-eight: 13 X 35 years = 455 menstrual cycles. 400,000-500,000 eggs divided by 455 = 879-1099.

[16] *See* J. PRITCHARD & P. MACDONALD, *supra* note 13, at 55.

It has been observed since the 1940's that for women with an average age of twenty-four, one out of every four menstrual cycles results in a clinically detectable pregnancy,[19] and that for women of age eighteen to twenty, one in ten pregnancies will end in a spontaneous abortion.[20] For women ages twenty-eight to thirty, it is estimated that only one out of every six to eight menstrual cycles will result in a clinically detectable pregnancy[21] and approximately 15% will end in spontaneous abortion.[22] The decline in fertility and the increase in the rate of spontaneous abortion rises year by year until, for women past the age of forty, it is estimated that 39% of all pregnancies end in spontaneous abortion.[23]

III. NATURAL OVULATION, FERTILIZATION, AND EMBRYO DEVELOPMENT

In the natural cycle one egg becomes dominant early in the menstrual cycle and blocks further development of all other eggs during that cycle.[24] In the *in vitro* fertilization cycle, fertility drugs are used to overcome this suppression so as to allow several eggs to develop and thereby increase the chance of a successful pregnancy. When the dominant egg has reached its full maturity in the natural cycle, it is released through action of the pituitary hormone

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[17] Menstrual cycles are often anovulatory during the first year after the onset of menses at puberty and during the years preceding menopause.

[18] Breast-feeding delays the return of ovulation after birth. Assume an average of three menstrual cycles before conception, nine months of gestation, and breast-feeding for nine to eighteen months: 3+9+(9 to 18)=21 to 30, 400 divided by 21 to 30=19 to 13 possible pregnancies (average 16).

[19] Diddle, Jack & Pearse, *Fertility in Women: The Length of Time Required to Conceive*, 54 Am. J. Obstet. Gynecol. 54 (1947) [hereinafter Diddle]; *see also* Guttmacher, *Factors Affecting Normal Expectancy of Conception*, 161 J. A.M.A. 855 (1956).

[20] Dickey, *Evaluation and Management of Threatened and Habitual First Trimester Abortion*, in 2 Advances in Clinical Obstet. & Gynecol. 7 (H. Osofsky ed. 1985).

[21] *See* Diddle, *supra* note 19.

[22] *See* Dickey, *supra* note 20.

[23] *Id.* at 9.

[24] *See* J. Pritchard & P. MacDonald, *supra* note 13, at 98; *see also id.* at 47.

LH.[25] Once released from the ovary, the egg enters the fallopian tube where it will reside for the next two days while fertilization and early development of the embryo take place.[26] Its entry into the fallopian tube is facilitated by the movement of cilia on the surface of the tube and perhaps by the ability of the tube to move to the site on the ovary where the egg is being released.[27] Once within the fallopian tube, the egg must mature an additional six hours and must undergo its final division from forty-six chromosomes to twenty-three chromosomes before fertilization can occur.[28]

A man ejaculates between 60 and 400 million sperm into the vagina during the marital act. Of this large number only a few thousand reach the egg in the fallopian tube.[29] Fertilization takes place in the wide portion of the fallopian tube nearest the ovary called the ampulla.[30] Before sperm can fertilize the egg, they must first penetrate through a wall of cells, the cumulus, which cushions, protects, and nourishes the egg while it is within the tube. When a single sperm has entered the egg, after some six to twelve hours,[31] fertilization is considered to have occurred.[32] Fusion of the separate sperm and egg genetic material does not occur in every instance.[33] Neither does division of the egg always occur. Once division to the eight to sixteen cell state has occurred, the fertilized egg, now called the embryo,[34] passes from the fallopian tube into the uterine cavity. This entire process, which occurs outside the uterus, requires two and one half days.[35]

After the embryo enters the uterine cavity, it will continue to divide until it reaches one hundred to one hundred twenty cells. At this stage, the embryo will hatch out of its capsule and implant in the lining of the uterus.[36] The uterine lining will have previously been stimulated by hormones, produced in the ovary, to develop an increased blood supply ready to nourish the embryo.[37] *In vitro* fertilization duplicates only that portion of gamete and embryonic existence which occurs outside the uterine cavity.[38] Once the embryo enters the uterine cavity, as a result of *in vitro* fertilization and embryo transfer, its subsequent development will be the same as occurs after passage from the fallopian tube during the natural cycle.

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[25] *Id.* at 47.

[26] *Id.* at 101.

[27] Pauerstein & Eddy, *The Role of the Oviduct in Reproduction: Our Knowledge and Our Ignorance*, 35 J. REPROD. FERT. 223-29 (1979).

[28] *See* J. PRITCHARD & P. MACDONALD, *supra* note 13, at 97-98.

[29] *Id.* at 102.

[30] *Id.*

[31] *Id.*

[32] *Id.* "As soon as the sperm penetrates the zona pellucida and touches the vitelline membrane, a second polar body is formed and the female pronucleus, as well as the male pronucleus, are evident in the ovum." *Id.*

[33] Edwards, Purdy, Steptoe & Walters, *The Growth of Human Preimplantation Embryos In Vitro*, 141 AM. J. OBSTET. GYNECOL. 408, 411 (1981) [hereinafter Edwards].

[34] *See* J. PRITCHARD & P. MACDONALD, *supra* note 13, at 105.

[35] *See* Pauerstein & Eddy, *supra* note 27. "Transport of ova in women is characterized by retention in the ampulla for approximately 27 hours followed by rapid transit through the isthmus. Ova are delivered to the endometrial cavity approximately 80 hours after release from the follicles." *Id.* at 224.

IV. SPONTANEOUS LOSS IN THE NATURAL REPRODUCTIVE CYCLE

Natural human reproduction is accompanied by a high loss rate among embryos. It is estimated that in the natural human cycle between 34% and 37% of the eggs which enter the fallopian tube are never fertilized.[39] Between 40% and 78% of eggs that are fertilized and enter the uterus will fail to implant or, if implanted, will not continue to grow and will be aborted either before the end of two weeks, the time of the expected menstrual period, or later in pregnancy.[40] These loss rates for human embryos are in the same range as have been observed for other primates and much higher than observed in some other species.[41] The cause of this high loss rate of fertilized human ova and early human embryos which occurs during the natural cycle is believed to be inherent within the eggs or the sperm themselves and thus has its origins many years or decades before the moment of conception. The high spontaneous loss rate in humans may be partially due to the age of the parents.[42]

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[36] *See* J. PRITCHARD & P. MACDONALD, *supra* note 13, at 107.

[37] *See id.* at 64.

[38] *See* Edwards, *supra* note 33.

[39] Biggers, *Risks of In Vitro Fertilization and Embryo Transfer in Humans*, in *In Vitro* Fertilization & Embryo Transfer 78, 83 (1983).

[40] Roberts & Lowe, *Where Have All the Conceptions Gone?*, 1 LANCET 498 (1975) (where the authors estimated a total embryonic and fetal loss of 78% by the time of birth); *see* Biggers, *supra* note 39, at 401 (using life table methods of analysis, the authors calculated that embryonic and fetal loss was 50% excluding loss due to fertilization failure), 404; Hertig, Rock, Adams & Menkin, *Thirty-four Fertilized Human Ova, Good, Bad, and Indifferent, Recovered from 210 Women of Known Fertility*, 23 PEDIATRICS 202 (1959) (found a loss in the first 17 days of 58% based on embryos washed from the uterus); Leridon, *Les Accidents Chromosomighes de la Reproduction*, Boue A. le Thibault C, 1973, 125-32 (the author estimates that of 100 ova exposed to spermatozoa *in vivo* only 31 would be expected to develop into live babies; he assumed a fertilization failure of 35% and a loss of embryos and fetuses of 52%); Miller, Williamson & Glue, *Fetal Loss After Implantation*, 2 LANCET 554 (1980) (using a radioimmunological assay for B-HCG in the urine, the authors found that the embryonic and fetal loss between the time of implantation and the 20th week of pregnancy was 43%); *see also* Rolfe, *Detection of Fetal Wastage*, 37 FERTILITY & STERILITY 655 (1982) (a wastage of 78% over the first two weeks based on blood test for early pregnancy factor was reported).

V. THE HISTORY OF HUMAN *IN VITRO* FERTILIZATION

Although the use of *in vitro* fertilization in animals dates back many years, the adoption of this process for women was slow to develop. After the first successful birth in 1978, it was nearly two years before a second baby was born in England.[43] Between 1978 and 1981, two additional clinics in Australia were also successful in having live births.[44] The early success rate was very low, perhaps one in thirty-five attempts.[45] In January, 1980, the first Certificate of Need was issued for an *in vitro* fertilization program in the United States to the Medical School of Eastern Virginia University at Norfolk. The first baby born in the United States as a result of this program was delivered on December 28, 1981, by cesarean section.[46] By March, 1985, there were 108[47] *in vitro* clinics registered in the United States and more than 200 worldwide. Of this number, in the United States only about thirty-eight clinics had achieved an *in vitro* pregnancy by March, 1985,[48] and only twenty-six clinics could report a live birth.[49]

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[41] *See* Biggers, *supra* note 39, at 82. Biggers reports embryonic loss in the Rhesus monkey as 14.3% in the preimplantation period and 28% in the two weeks after implantation. In the baboon, embryonic loss in the preimplantation period was 25% and in the post-implantation period, the two weeks after implantation, was between 14.3% and 33.3%. In the cow which he had extensively studied, he found the embryonic and fetal loss combined to be 20%.

[42] *See* Diddle, *supra* note 19.

[43] Steptoe, Edwards & Purdy, *Clinical Aspects of Pregnancies Established with Cleaving Embryos Grown In Vitro*, 87 BRIT. J. OBSTET. GYNECOL. 757 (1980) [hereinafter Steptoe].

[44] Lopata, Johnston, Hoult & Speirs, *Pregnancy Following Intrauterine Implantation of an Embryo Obtained by In Vitro Fertilization of a Preovulatory Egg*, 33 FERTILITY & STERILITY 117 (1980); *see also* Trounson, Leeton, Wood, Webb & Wood, *Pregnancies in Humans by Fertilization In Vitro and Embryo Transfer in the Controlled Ovulatory Cycle*, 212 SCIENCE 681 (1981).

[45] *See* Steptoe, *supra* note 43.

[46] Jones, Jones, Andrews, Acosta, Bundren, Garcia, Sandow, Veeck, Wilkes, Witmyer, Wortham & Wright, *The Program for In Vitro Fertilization in Norfolk*, 38 FERTILITY & STERILITY 14 (1982).

[47] *IVF: A Game for Losers at Half of U.S. Clinics*, Medical Tribune, July 3, 1985, at 1, col. 2 [hereinafter Medical Tribune].

In Louisiana, the first Certificate of Need for an *in vitro* fertilization program was issued to a community hospital in January, 1983.[50] The first successful egg retrieval and embryo transfer was performed in September, 1983.[51] The first birth of a baby conceived by *in vitro* fertilization in Louisiana occurred on June 18, 1984. One month later the second baby was born. At the time of the second birth in Louisiana, there were still fewer than 800 *in vitro* births in the world. As a result of a single Louisiana *in vitro* fertilization program, fifteen babies had been born as of October 1, 1985, including two sets of twins and one set of triplets.[52]

VI. TECHNIQUES AND VARIATIONS OF THE *IN VITRO* FERTILIZATION PROCEDURE

The basic technique of *in vitro* fertilization duplicates in the laboratory the natural process of fertilization and development within the fallopian tube. In a first step, the development of multiple eggs is stimulated through use of the fertility medications, clomiphene citrate and human menopausal gonadotropin. This stimulation enhances the possibility that a single surgical procedure for the mother will result in a pregnancy.[53] The development of the egg and the administration of the hormones must be closely

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[48] *Id.*

[49] *Id.*

[50] Dickey, Taylor, Curole & Bordson, *The First In Vitro Fertilization Pregnancy in Louisiana*, 136 La. St. Med. Soc'y 11 (1984) [hereinafter Dickey].

[51] *Id.*

[52] These included nine boys and six girls.

[53] The possibility that a clinical pregnancy will occur following embryo transfer is directly proportional to the number of good quality embryos that are transferred, but does not increase after transfer of three good quality embryos. At the Fertility Institute of New Orleans, results are as follows:

	Pregnancy Rate	Percent Twins	Percent Triplets
One embryo transferred	10.3%	0	0
Two embryos transferred	18.3%	11.1%	0
Three embryos transferred	37.5%	11.1%	0
Four or more embryos transferred	35.3%	0	5.9%
Average	14.9%		
Abortion Rate	11.5%	per pregnancy	
Continuing pregnancy rate	13.2%		

Compare the following:

1. Lopata, *Concepts in Human In Vitro Fertilization and Embryo Transfer*, 40 Fertility & Sterility 289 (1983):

monitored by the use of ultrasound and hormone assays.

	Pregnancy Rate	Percent Twins
One embryo transferred	11.2%	0
Two embryos transferred	18.6%	15.8%
Three embryos transferred	22.6%	7.1%
Four embryos transferred	28.6%	35.3%
Five embryos transferred	14.53%	0
Average pregnancies per laparoscopies	14.8%	
Abortion Rate	45.4%	
Continuing pregnancy per laparoscopy	8.1%	

2. Wood, *supra* note 9, at 248:

	Rate
One embryo transferred	7.0%
Two embryos transferred	20.2%
Three embryos transferred	26.3%
Four embryos transferred	22.6%
Average per laparoscopy	10.0%

3. Jones, *supra* note 9, at 831:

	Pregnancy Rate	Percent Twins*
One embryo transferred	20%	5.0%
Two embryos transferred	23%	13.0%
Three embryos transferred	29%	10.3%
Four embryos transferred	39%	15.4%
Five embryos transferred	19%	31.6%
Six embryos transferred	50%	50.0%
Average per laparoscopy	18.8%	*(Also 15.4% triplets)
Abortion Rate	13.4% per pregnancy	
Continuing pregnancy rate	12.8%	

4. Yovich, *Embryo Quality and Pregnancy Rates in In Vitro Fertilization*, 1 LANCET 283 (1985):

	Pregnancy Rate	Percent Twins	Percent Triplets
One embryo transferred	7.9%	0	0
Two embryos transferred	20.8%	27.3%	0
Three embryos transferred	25.0%	16.7%	16.7%
Four embryos transferred	22.8%	12.5%	12.5%
Five embryos transferred	55.5%	60.0%	20.0%
Six embryos transferred	33.0%	100%	
Average per laparoscopy	14.0%		
Abortion Rate	NA		

5. Craft, Porter, Green, Tucker, Smith, Twigg, Ahuja & Whittingham, *Success of Fertility, Embryo Number, and In Vitro Fertilization*, 1 LANCET 732 (1984):

	Pregnancy Rates	Percent Multiple Pregnancies
One embryo transferred	6.5%	0
Two embryos transferred	26.0%	9.5%
Three embryos transferred	19.0%	18.2%
Four embryos transferred	21.0%	16.7%
Five embryos transferred	29.0%	25.0%
Six embryos transferred	40.0%	50.0%
Average per laparoscopy	NA	

In the second step, the eggs are retrieved from the ovary through a surgical procedure, laparoscopy, which requires general anesthesia and the insertion of an instrument through the navel to visualize the eggs, with additional instruments used to stabilize the ovary and withdraw the fluid containing the eggs from the ovaries.[54] Another technique utilizes a needle guided by ultrasound which is passed through the abdominal wall and the bladder in order to withdraw fluid from the ovary.[55] The ultrasound technique may result in the recovery of fewer eggs.[56]

Once the eggs have been recovered, they are transported to the laboratory where they are transferred into a fluid similar to that found in the fallopian tube.[57] The eggs are allowed to mature in this fluid for six hours. At the end of six hours, sperm which has previously been collected from the husband and then processed, to complete its maturation, is added to the egg, usually in a ratio of 50,000 sperm per egg.[58] The egg and sperm are then returned to the incubator where they remain for the next twelve hours in order for fertilization to take place. When it is determined that an egg has been fertilized, the egg is placed into a growth media and allowed to develop by division until it reaches a stage between two and eight cells. Once it has reached the two-to-eight-cell stage the fertilized ovum, now called an embryo, is removed from the media and introduced into the uterus of the mother through a catheter threaded through the cervix without anesthesia.[59]

Usually progesterone hormones are administered following ovum retrieval in order to increase the development of the lining of the uterus and make it more receptive for the embryo.[60] From the time the embryo is introduced into the uterus, the pregnancy proceeds in an entirely normal manner. The entire process from retrieval of the eggs to transfer of the embryo into the uterus takes fifty to seventy-eight hours and is nearly identical to the time from ovulation to entry of the embryo into the uterus which occurs during the natural human reproductive cycle.[61]

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[54] *See* Dickey, *supra* note 50.

[55] Wikland, *Collection of Human Oocytes by the Use of Sonography*, 39 FERTILITY & STERILITY 603 (1983); *see also* Parsons, *Oocyte Retrieval for In Vitro Fertilization by Ultrasonically Guided Needle Aspiration Via the Urethra*, 1 LANCET 1076 (1985).

[56] *Id.*

[57] *See* Dickey, *supra* note 50.

[58] *Id.*

[59] *Id.* At the Fertility Institute of New Orleans, all embryos are transferred into the uterus. Transfer of low quality embryos along with high quality embryos does not decrease the possibility that high quality embryos will implant so long as the total number does not exceed three embryos transferred. *Id.*

[60] *See id.*

Various combinations of IVF and embryo transfer are possible. One listing is the following:

I. *In vitro* fertilization without embryo transfer;
II. *In vitro* fertilization with subsequent embryo transfer;
III. *In vivo* fertilization and subsequent embryo transfer (recovering the embryos from the uterus of the donor);
  a. Fertilization by means of mating;
  b. Fertilization by means of artificial insemination.[62]

To these may be added other variations including: (1) *In vitro* fertilization with sperm from a donor, other than the husband; (2) Donation of an egg by one woman for fertilization by the husband of another woman with transfer into the uterus of the other woman.

Yet another variation is Gamete Intra-Fallopian Transfer or GIFT.[63] In the GIFT procedure eggs are retrieved from the ovary by laparoscopy and taken to the laboratory where they are separated from their surrounding liquid. Eggs and previously prepared sperm are then introduced into the fallopian tubes during the same laparoscopy. In GIFT, fertilization and early embryo development take place in the fallopian tubes rather than in the laboratory.

The remainder of this paper will be concerned only with *in vitro* fertilization and embryo transfer into the uterus of the donor or into the uterus of another female. Medical reasons for transfer of the embryo into the uterus of a woman other than the egg donor are present in the situations where the donor of the egg is incapable of carrying a pregnancy to full term either because of a defect in the uterus which has caused repeated spontaneous abortions,[64] because of the absence of the uterus due to previous surgery with the retention of the ovaries, or because of severe and life threatening medical conditions of the egg donor which would seriously impair the donor's health if she were to carry a pregnancy to term. Life threatening conditions include cancer of the breast, uterus, cervix, or blood system, severe cardiovascular disease, or a serious debilitating illness for which pregnancy would be life threatening.[65] Although transfer of the embryo fertilized during *in vitro* fertilization into the uterus of a woman other than the egg donor has been successfully accomplished only a few times, all outside the United States,[66] such a procedure is well within the medical capabilities of most *in vitro* laboratories. For the above valid medical uses, transfer of embryos into the uterus of a woman other than the egg donor, also called a surrogate, should be given consideration in any discussion of the legal considerations of *in vitro* fertilization. The fertilization of an *in vitro* egg by sperm other than the husband's, and transfer into the uterus of the egg donor is, in many respects, similar to cervical or intrauterine artificial insemination with donor sperm which is recognized legally in most states, including Louisiana.[67]

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[61] *Id.; see also* Pauarstein & Eddy, *supra* note 27.

[62] Protection of Human Subjects: HEW Support of Human *In Vitro* Fertilization and Embryo Transfer: Report of the Ethics Advisory Board, 44 Fed. Reg. 35,033 (1979).

[63] Asch, Ellsworth, Balmaceda & Wong, *Pregnancy After Translaparoscopic Gamete Intrafallopian Transfer*, 2 LANCET 1034 (1984).

[64] *See* Dickey, *supra* note 20, at 13.

VII. GUIDELINES FOR *IN VITRO* FERTILIZATION

Because of the need for *in vitro* fertilization and embryo transfer by large numbers of infertile couples, the American College of Obstetrics and Gynecology and the American Fertility Society have adopted identical guidelines regarding the qualifications of personnel and the types of facilities that are necessary to provide optimal chances for the successful outcome of *in vitro* fertilization and embryo transfer (IVF-ET).[68]

These guidelines include the review of all aspects of the *in vitro* program by an institutional review committee or its equivalent, whether performed in a private community hospital or a university-based medical center.[69] The guidelines state that accurate data and records covering all aspects of the medical treatment cycles must be kept, including the success or failure of oocyte recovery, fertilization, cleavage, conceptus transfer, physical monitoring of fetal growth, pregnancy, pregnancy outcome, and complications that may occur during egg recovery, during laparoscopy, or after egg culturing or any problems during or after pregnancy. Maintenance of such records should be confidential.

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[65] *See* J. Pritchard & P. MacDonald, *supra* note 13, at 701 (Chapter 28: "Medical and Surgical Illnesses during Pregnancy and the Puerperium").

[66] One anecdotal case in Australia involved the donation of an embryo by a woman undergoing *in vitro* fertilization. The woman receiving the donated embryo conceived. However, the donor failed to get pregnant.

[67] Lorio, *In Vitro Fertilization and Embryo Transfer: Fertile Areas for Litigation*, 35 Sw. L.J. 973, 973 (1982); *see also* La. Civ. Code Ann. art. 188 (West Supp. 1986).

[68] American College of Obstetricians and Gynecologists, Committee on Gynecologic Practice, Human *In Vitro* Fertilization and Embryo Placement (April 1984) [hereinafter ACOG Committee].

[69] *Id.*

Recommended personnel requirements include expertise in four skilled areas: (A) a person to direct the program who has training or board certification in reproductive endocrinology[70] (a basic laboratory scientist who has experience in laboratory work or embryology in the human or animal field would not be an acceptable director); (B) a surgeon with expertise in operative laparoscopy procedures and ability and training in oocyte aspiration; (C) a Ph.D. or M.D. experienced in male reproductive physiology with special competence in semenology; and (D) an individual, preferably with a doctorate degree, with knowledge and working experience in tissue culture, gamete maturation, fertilization, and cleavage in human concepti as well as knowledge of animal systems. These skills may be concentrated in one or two individuals or may be spread among four or more.

The guidelines further state: (A) ultrasonography must be available seven days a week; (B) operating room facilities necessary for laparoscopic retrieval may be found either in an outpatient surgical center or a hospital inpatient operating theater design; (C) the operating room availability must be rigidly controlled so that patients can be moved in and out seven days per week with a maximum of twenty-four hour notice; (D) anesthesia must be available seven days per week; (E) in the laboratory, rapid hormonal assay systems capable of measuring estradiol and luteinizing hormones must be available seven days per week; (F) a facility for oocyte and sperm culturing should be close to the operating room with two-way communication; (G) necessary equipment must include an incubation system, magnification system for identifying oocytes and embryos and a system to maintain quality control of media preparations from week to week.[71] Most commonly, mouse embryo growth development rates are used to determine the safety of media for use in the human egg systems.

These recommendations conclude that, if the aforementioned guidelines are followed, a program of IVF-ET can be established in a private setting as well as in university-based hospital systems.

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[70] *Id.*

[71] *Id.*

However, it should be cautioned that the procedure itself is very complex and highly technical and requires a large backup system of laboratory support and specialized personnel available seven days per week.[72]

VIII. SELF REGULATION OF *IN VITRO* FERTILIZATION

In the absence of governmental regulations, the majority of *in vitro* fertilization clinics have established their own regulations based on their individual and community standards. Throughout most of the United States, and in Louisiana, there is the basic recognition that all embryos are actual or potential human life. This position mandates the replacement of all embryos into the uterus, the only site in which they can develop to maturity. To a large extent, the fulfillment of the guidelines of the American College of Obstetrics and Gynecology (ACOG) and the American Fertility Society (AFS) regarding equipment, personnel and record keeping have been left to the individual clinics. The first IVF clinic to open in Louisiana fulfills all the requirements of ACOG and AFS guidelines.[73] The only state action to date in Louisiana has been the issuing of a certificate of need to hospitals in which *in vitro* fertilization is to be performed. The first certificate of need was issued in January, 1983, to a community hospital in New Orleans.[74]

IX. PRESENT STATUS OF *IN VITRO* FERTILIZATION (PREGNANCY RESULTS)

In a recent national survey conducted in March, 1985, of 108 clinics in the United States, only twenty-six clinics reported having had a live birth by *in vitro* fertilization.[75] A small number of clinics are highly successful. In these clinics, pregnancy rates of 10% to 15% are achieved per laparoscopy for egg retrieval.[76] Of the number that become pregnant, between 55% to 88% successfully carry their pregnancy to term.[77] There is another group of clinics where a 3% to 5% pregnancy rate has been common. An unknown number of clinics have closed without ever achieving a pregnancy. A further breakdown of results at one successful *in vitro* fertilization clinic reveals that approximately 98% of patients have at least one egg retrieved at laparoscopy, 57% of retrieved eggs are fertilized, 79% of embryos develop and 78% of patients have the transfer of at least one high quality embryo that could result in a pregnancy.[78] The pregnancy rate in the first IVF clinic in Louisiana is 14.9% for all patients who have laparoscopy and 19.1% for all patients who have at least one good embryo transferred.[79]

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[72] *Id.*

[73] *See id.*

[74] *See* Dickey, *supra* note 50.

[75] *See* Medical Tribune, *supra* note 47.

[76] *See supra* note 53.

[77] *Id.*

The pregnancy rate is highly dependant on the number of good to excellent quality embryos that are transferred into the uterus.[80] In the first Louisiana clinic, as well as worldwide, experience has shown that the rate of pregnancy increases as the number of good quality embryos transferred increases from one to three. When four or more embryos are transferred, the pregnancy rate does not increase further and may decrease.[81] Thus, the additional embryos, transferred after the third embryo, do not have an equal chance to implant and may even impair the chance of the other embryos to develop. Pregnancy rates are on the order of 10% for the transfer of one embryo, 25% for the transfer of two embryos, and 35% to 40% for the transfer of three embryos, with no increase above that number.[82]

An additional problem of multiple embryo transfer is the increased chance of multiple pregnancy. Through March, 1985, there had been twenty-three sets of twins and four sets of triplets born in the United States.[83] In other countries, the birth of quadruplets as a result of IVF has been reported. Although twins are not usu-

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[78] Fertility Inst. of New Orleans, Summary Results (1985). The results from 1983 to August 31, 1985, are as follows:

Laparoscopies	175
Patients with eggs	98%
Eggs Fertilized	57%
Fertilized Eggs that Divided	79% (55% of Retrieved)
Patients with at least one good embryo transfer	136 (78% of laparoscopy)
Pregnancies	26
Pregnancies per laparoscopy	14.9%
Pregnancies per transfer of good quality embryo	19.1%
Delivered or continuing pregnancies per laparoscopy	13.1%

[79] *Id.*

[80] *Id.*

[81] *See supra* note 53.

[82] *Id.*

[83] *See* Medical Tribune, *supra* note 47.

ally a problem, all multiple pregnancies invite the likelihood of premature births. Since March, 1985, there have been two sets of twins and one set of triplets born in Louisiana. In the case of the triplets, four good to excellent quality embryos were transferred. Of the twins in Louisiana, one set resulted from the transfer of two good quality embryos and the other from the transfer of five excellent quality embryos. In order to obviate the problem of multiple pregnancy due to the transfer of increased numbers of high quality embryos, most successful *in vitro* fertilization programs in the United States have developed or are developing the capability for embryo freezing.[84]

Other means of limiting the numbers of embryos transferred into the uterus are (1) limiting the number of eggs retrieved from the ovary;[85] (2) limiting the number of eggs that are allowed to be fertilized;[86] or (3) freezing excess eggs as is done for sperm.[87] Unfortunately, none of these methods are practical. The retrieval and fertilization of multiple eggs is a necessary part of a successful *in vitro* program.[88] In two of the twenty-six successful *in vitro* pregnancies in Louisiana, only a single egg of the seven or eight eggs that were retrieved from the ovary developed into an embryo. In one case, it is known with certainty that this was the last of eight eggs retrieved from the ovary. To reduce the number of eggs retrieved to two, three or four would seriously impede the possibility of successful pregnancy as a result of the IVF procedure.[89] A plan to fertilize only three or four of the eggs retrieved from the ovary has the same drawback because there is no guarantee that any particular egg will develop into an embryo after exposure to sperm. Neither is there any assurance that all four will not develop into good to excellent embryos and result in a triplet or quadruplet pregnancy.[90] Freezing the human egg before fertilization has proven to be very difficult due to its large size. Only one instance of successful freezing and subsequent thawing, fertilization, and development of human egg into an embryo has been reported.[91] No pregnancy resulted in this case.

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[84] *Id.*

[85] *See* Lorio, *supra* note 67, at 978 n.44. Dr. Martin Quigley stated that at the University of Texas Medical Center only two eggs are removed from the mother.

[86] Kramer, *Last Chance Babies*, N.Y. Mag., August 12, 1985, at 40. "Norfolk transfers back every egg it fertilizes. The limit is six. If laparoscopy yields more than six mature eggs that appear equally healthy, the first six are fertilized." *Id.*

[87] Bernard, *Effects of Cryoprotectants on Human Oocyte*, 1 Lancet 632 (1985).

[88] *See supra* note 53.

[89] *See supra* note 53 (Yovich reported that the incidence of triplets was 16.7%, 12.5% and 20% of pregnancies when three, four, or five embryos respectively were transferred. Also, Jones reported triplets in 15.4% of pregnancies when four embryos were transferred.).

[90] *See* Bernard, *supra* note 87.

X. NEW DEVELOPMENTS IN *IN VITRO* FERTILIZATION AND EMBRYO TRANSFER

A. Embryo Freezing

The next technique to receive widespread use in *in vitro* fertilization and embryo transfer may well be embryo freezing. There are two reasons why embryo freezing is considered necessary. The first is to obviate multiple pregnancies.[92] The second is the situation in which an embryo cannot be transferred into the uterus during the cycle of ovum retrieval with reasonable possibility of success because of high fever, bleeding, accidental injury to the mother or a natural disaster, such as a hurricane. Every *in vitro* program must face the possibility that this can happen and, we believe, should be prepared with an emergency embryo freezing procedure in order to preserve the possibility of life for the embryo.[93] Already there have been eleven successful pregnancies following transfer of frozen embryos in Australia[94] and England.[95] Recent studies in humans suggest that the optimal time for freezing the human embryo is at the 100 plus cell stage when the embryo is beginning to hatch out of the zona pellucida.[96] Approximately 35% of embryos do not survive the freeze-thaw process.[97]

New laws are needed to cover the multiple possibilities that can occur while an embryo exists in the frozen state. These possibilities include the death, permanent disablement or divorce of the donor mother, as occurred in a celebrated case in Australia, or a change of mind by the donor mother and husband due to economic or family circumstances, including the birth of a desired child or the desire not to have additional children. Because of the need for embryo freezing to maximize the possibility of each embryo's survival and because of the multiple possibilities which can occur while the embryo is in the frozen state, new laws are urgently needed to protect institutions, physicians, and infertile couples.

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[91] *See supra* note 53.

[92] Mohr, Trounson & Freemann, *Deep-Freezing and Transfer of Human Embryos*, 2 J. IN VITRO FERTILIZATION & EMBRYO TRANSFER 1 (1985) (the transfer of 68 thawed embryos into 45 patients resulted in 9 pregnancies); *see also* Cohen, Simons, Edwards, Fehilly & Fishel, *Pregnancies Following the Frozen Storage of Expanding Human Blastocysts*, 1 J. IN VITRO FERTILIZATION & EMBRYO TRANSFER 59 (1985) (two pregnancies resulted from transfer of thawed embryos to 11 patients).

[93] *See* Cohen, *Birth After Replacement of Hatching Blastocyst Cryopreserved at Expanded Blastocyst Stage*, 1 LANCET 647 (1985) (transfer of fifteen thawed embryos frozen at the expanding blastocyst stage resulted in eight pregnancies, 53%).

[94] *Id.*

[95] *Id.*

[96] *Id.*

[97] *Id.*

B. Donation of Eggs

The second development which is on the immediate horizon as a result of IVF is the donation of an egg from one woman who is fertile to another woman who is infertile, because of premature ovarian failure or the surgical removal of her ovaries, for the purpose of fertilization by either the husband of the infertile woman or another man. This procedure is within the capability of all IVF laboratories now. The legal ramifications regarding actual genetic parenthood versus birth parenthood needs to be resolved before such procedures are undertaken. Ideally, all such eggs would be donated without payment to the donor with the possible exception of coverage of medical expenses.

C. Transfer of an Embryo into a Surrogate Mother

A third development which is within the capability of many IVF programs is the transfer of an embryo which resulted from an egg donated by the wife fertilized by her husband's sperm into the uterus of another woman, i.e., a surrogate uterus, or mother, in order that a pregnancy may successfully proceed to term. Medical indications for this procedure are (a) a woman who has spontaneously aborted all her pregnancies, or (b) a woman who cannot carry a pregnancy to term due to health reasons. In such a situation, the resulting baby would be clearly the genetic progeny of the husband and wife who furnish the sperm and egg. Current laws, however, would give the baby to the surrogate or birth mother and her husband if she is married. This situation is entirely different from two other techniques currently practiced in the United States. In one of these, the surrogate is impregnated by artificial insemination with the husband's sperm and carries the pregnancy to term. In the second, the surrogate is artificially inseminated with the husband's sperm, or sperm from a donor, and the embryo is flushed out of the uterus before it has the opportunity to implant. The embryo is then transferred into another woman, usually the wife of the man whose sperm was used for insemination.

IVF using the egg and sperm of husband and wife with embryo transfer into the uterus of a healthy woman in order for pregnancy to reach term obviates many of the objections to these last two procedures but in turn raises new problems. The legal problems raised by use of a surrogate uterus must be resolved if the new medical technologies are to be allowed to prevent repeated abortions due to uterine defects, not correctable by surgery, and to obviate the terrible necessity of a woman with a life threatening medical condition having to choose between having an induced abortion or losing her own life.

XI. SUMMARY

In vitro fertilization and embryo transfer is a compassionate and ethical technological breakthrough which permits pregnancy to occur where before there had been no hope. Most infertility requiring *in vitro* fertilization is an acquired condition. Most women and their husbands who require IVF were not born infertile, but became infertile during the delay between the time they reached sexual maturity and the time they were economically ready to marry and bear children. *In vitro* fertilization is a conservative procedure which permits the human egg and sperm to complete the act for which they were intended, that is union and the reproduction of human life. If IVF were not done, eggs and sperm would be lost and the marital act would not only be ineffectual in achieving procreation but would be doubly frustrating to the married couple in that the marriage would be without hope of issue. The results of *in vitro* fertilization in terms of the ratio of eggs exposed to fertilization and embryos transferred which result in pregnancy, although apparently poor, are, in successful IVF programs, well within the range that occurs in the natural human reproductive cycle. In the natural cycle approximately 10,000 eggs and 20 billion sperm are expended for each human birth, and 70% to 80% of all fertilized eggs and 50% to 70% of all embryos fail to develop into a pregnancy that results in a live birth. Embryo freezing is necessary for both the conservation of the embryo and the prevention of excessive multiple pregnancies. Developments such as ovum donation and surrogate uteri are both compassionate and medically sound, and enable life to occur where it could not otherwise do so.

In view of its great potential for enhancing life, it is especially important that appropriate changes be made in present laws in order to deal with the new situations created by IVF and ET.

IVF/GIFT SURVEY

CLINIC NAME: Fertility Center of Louisiana
ADDRESS: 200 West Esplanade Avenue - Suite #210
Kenner, Louisiana 70065

CONTACT PERSON: Heber E. Dunaway, Jr., M.D.
PHONE NUMBER: (504) 464-8622

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Feb.1989

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians ________
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 3
   - (e) Other Lab Technicians/Technologists 3
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors ________
   - (h) Secretaries 3
   - (i) Other (specify) 2 (Graduate Students)

7. How many years has your infertility clinic been in operation? June 1985

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF May 1987 GIFT May 1987

9. How many different patients were stimulated?
1987 IVF 88 1988 IVF 89
GIFT 14 GIFT 11

10. How many stimulation cycles were performed?
1987 IVF 119 1988 IVF 105
GIFT 20 GIFT 15

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 101 1988 91

How many embryo transfer cycles were performed?
1987 85 1988 82

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 20 1988 15

13. What were the number and percentage of patients on IRB approved research protocols?
1987 -0- % 1988 -0- %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 42 47 % 1988 IVF 37 41 %
GIFT 0 0 % GIFT 0 0 %
*(b) Endometriosis:
1987 IVF 20 22 % 1988 IVF 17 19 %
GIFT 4 28 % GIFT 6 54 %
(c) Male infertility:
1987 IVF 35 39 % 1988 IVF 39 43 %
GIFT 0 0 % GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 11 12 % 1988 IVF 12 13 %
GIFT 11 78 % GIFT 9 81 %
(e) Other (explain): ____________________
1987 IVF 0 ___ % 1988 IVF 0 ___ %
GIFT 0 ___ % GIFT 0 ___ %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 15 17 % 1988 IVF 17 19 %
GIFT 4 28 % GIFT 5 45 %
(b) 31-35:
1987 IVF 26 29 % 1988 IVF 22 24 %
GIFT 4 28 % GIFT 3 27 %
(c) 36-40:
1987 IVF 41 46 % 1988 IVF 46 51 %
GIFT 5 35 % GIFT 3 27 %

---

* Numbers reflect some overlap of diagnosis

(d) 41-45:
1987 IVF 6 6 % 1988 IVF 4 4 %
GIFT 1 7 % GIFT ___ ___ %
(e) >45:
1987 IVF ___ ___ % 1988 IVF ___ ___ %
GIFT 0 ___ % GIFT ___ ___ %

16. How many clinical pregnancies were produced?
1987 IVF 22 1988 IVF 24
GIFT 5 GIFT 3

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 15 1988 IVF 12
GIFT 3 GIFT 2

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 8
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 3
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 5 33% 5 sets twins
GIFT 1 33 % 1 set twins

1988 IVF 3 25% 3 sets twins
GIFT 0 0 % -0-

21. What are the qualifications of the director of the embryo laboratory? Ph.D.

22. Who supervises the laboratory director? Brenda L. Bordson, Ph.D.

23. Does the clinic participate in an external laboratory proficiency testing program? Yes, CAP
If the answer is yes, please specify which program.
CAP & AATB: College of American Pathologists, American Association of Tissue Banks.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No, at present; but negotiations are underway with Tulane Medical Center OB/GYN and Ochsner Foundation.

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) 2
    (c) Embryo laboratory technicians/technologists 6
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

See attached.

28. We feel that our in-vitro fertilization clinic is one of the finest in the nation for the following reasons.

1) Our clinical pregnancy rate has consistently been above 25%.

2) We care for a significant number of couples with severe oligospermia (approximately 40% of our population over the past two years).

3) Our statistics reflect all couples who have been cycled for either in-vitro fertilization and/or G.I.F.T. No patients or cycles have been omitted.

4) Our live birth rate is in excess of 15% per cycle for both years 1987 and 1988.

5) Our laboratory director and lab is recognized for her excellence nationally and consults on a retainer basis with approximately six in-vitro fertilization labs in the country.

6) Our pregnancy rate since the inception of luteal phase lupron starts is approximately 40% (reflects approximately fifty patient cycles).

Our numbers also indicate a strong predilection for in-vitro fertilization over G.I.F.T. This is primarily for the following reasons.

1) The majority of our patient population is a referral population with again a strong skewing toward male and tubal factor related infertility.

2) Our criteria for G.I.F.T. is very stringent with all couples undergoing at least three cycles of controlled ovarian hyperstimulation combined with intrauterine insemination prior to the recommendation of G.I.F.T. Our good success with this modality has decreased the number of patients undergoing the G.I.F.T. procedure.

3) Our pregnancy rate with in-vitro fertilization is comparable to G.I.F.T. which we feel reflects the excellence of our in-vitro program and our stringent requirements for G.I.F.T.

IVF/GIFT SURVEY

CLINIC NAME: Tulane Medical Center Fertility Clinic
ADDRESS: 1415 Tulane Avenue
New Orleans, LA 70112

CONTACT PERSON: Ian H. Thorneycroft
PHONE NUMBER: (504)588-2341

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? _____

2. Does your clinic perform IVF/GIFT treatments? _______
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ✓
   - (b) Community hospital based ________
   - (c) University based ✓
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians 6
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists ________
   - (f) Radiology (Ultrasound) Technicians ________
   - (g) Psychologists/Counselors ________
   - (h) Secretaries 1
   - (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 6

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1985 GIFT 1987

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF _______
GIFT _____ GIFT ______

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF _______
GIFT _____ GIFT ______

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ________ 1988 ________

How many embryo transfer cycles were performed?
1987 ________ 1988 ________

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ________ 1988 _________

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ 50% 1988 IVF ___ 10%
GIFT ___ 0% GIFT ___ 0%
(b) Endometriosis:
1987 IVF ___ 30% 1988 IVF ___ 20%
GIFT ___ 40% GIFT ___ 40%
(c) Male infertility:
1987 IVF ___ 10% 1988 IVF ___ 10%
GIFT ___ 10% GIFT ___ 10%
(d) Unexplained infertility:
1987 IVF ___ 10% 1988 IVF ___ 10%
GIFT ___ 50% GIFT ___ 50%
(e) Other (explain): ______________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

19. How many ectopic pregnancies resulted?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ____________________
GIFT ___ ___% ____________________

1988 IVF ___ ___% ____________________
GIFT ___ ___% ____________________

21. What are the qualifications of the director of the embryo laboratory? [illegible] embryo and sperm manipulation

22. Who supervises the laboratory director? Dr. [illegible]

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No ________________

27. Does the clinic train individuals in IVF or GIFT? Yes, ______
If the answer is yes, how many individuals in the following specialties have been trained?
    - (a) Physicians ________
    - (b) Laboratory scientists (PhDs) _______
    - (c) Embryo laboratory technicians/technologists _____
    - (d) Nurses _______
    - (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The areas of the survey not completed by me have been deliberately not completed. The data base collection of this survey is invalid from the start. It assumes that everyone who is reporting data is using the same standards in recruiting patients. This clearly varies from one clinic to another. One clinic might do GIFT in a patient who has been trying for six months, whereas other clinics may restrict GIFT to those who have been trying for two to three years without any cause for infertility. Obviously, the pregnancy rates between those two clinics will be quite different. Clinics whose pregnancy rate may be temporarily elevated or whose pregnancy rate is higher than anothers because of a difference in patient selection, could easily use the numbers in newspaper advertising, which is quite common today, to seek an economic advantage for their clinic.

I feel the survey is good and may identify problems, but since the accuracy of the data recorded by clinics cannot be verified, I think each clinic should identified by a number, then the numbers compared and the government derive whatever information it wishes for legislation. Those patients who wish to know a clinics numbers should discuss them at the time of a professional consultation.

IVF/GIFT SURVEY

CLINIC NAME: UNIVERSITY OF MARYLAND AT BALTIMORE
ADDRESS: OB-GYN ASSOCIATES
419 WEST REDWOOD STREET - ST. 500
BALTIMORE, MD 21201

CONTACT PERSON: EUGENE KATZ, MD
PHONE NUMBER: (301) 328-2304

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Dec. 88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based ✓
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians 2
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 0
   - (e) Other Lab Technicians/Technologists 0
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 4 MONTHS

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF September 88 GIFT September 88

- 2 -

9. How many different patients were stimulated?
1987 IVF 0 1988 IVF 2
GIFT 0 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 0 1988 IVF 3
GIFT 0 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 0 1988 2

How many embryo transfer cycles were performed?
1987 0 1988 1

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 0 0 % 1988 IVF 2 100 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 1 100 %
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %
(e) Other (explain): ____________________
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %
(b) 31-35:
1987 IVF 0 0 % 1988 IVF 2 100 %
GIFT 0 0 % GIFT 1 100 %
(c) 36-40:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 %
GIFT 0 0 %

1988 IVF 0 0 %
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? Associate Professor in Anatomy/Physiology. Extensive Lab. experience with pig/mouse embryos and Granulosa cells

22. Who supervises the laboratory director? Eugene Katz, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** NO

27. **Does the clinic train individuals in IVF or GIFT?** 0
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) **Physicians** 2
    (b) **Laboratory scientists (PhDs)** 0
    (c) **Embryo laboratory technicians/technologists** 0
    (d) **Nurses** 0
    (e) **Other (explain)** 0

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

The IVF/GIFT program at the University of Maryland initiated its activites in September of 1988. The number of patients to be treated in early 1989 will increase substantially the number of patients treated since its inception. The program offers cryopreservation of embyros for selected couples. The laboratory is staffed by two Ph.D. Faculty members of the University of Maryland.

THE UNIVERSITY OF MARYLAND

SCHOOL OF MEDICINE
Obstetrics and Gynecology

Division of Reproductive Endocrinology
Eli Y. Adashi, M.D., Director

RECEIVED
DEC 14 1988
Hon Ron Wyden

December 9, 1988

Ron Wyden
Chairman
Subcommittee on Regulation & Business Opportunities
Congress of The United States
House of Representatives
Suite 1406
Longworth House Office Building
Washington, DC 20515
Attention: D. Ann Murphy

Dear Mr. Wyden:

Enclosed please find the IVF/G.I.F.T. survey I received in November of this year. I strongly support your efforts in regulating the treatment of the infertile couple in the United States. I am afraid however, the data gathered through this survey will have a significantly negative impact on the operation of newer programs. On the one hand the information on our program that you plan to subsequently distribute to patients will be totally out dated by the time it is published. For instance the number of patients undergoing these procedures in our institution during 1988 will be quadrupled in just one month namely in January 1989. Moreover, the negative impact will be long lasting since I do not expect you to update the information to patients on a bi-annual basis. Rather than Congress publishing report cards on each specific clinic I feel it is more important to educate the patient as to what questions to ask in choosing an infertility program.

Sincerely,

Eugene Katz, M.D.
Director
ART Program
Assistant Professor
Obstetrics and Gynecology

Enclosure
EK:ty

CAMPUS FOR THE PROFESSIONS
Room 11-007, Frank C. Bressler Research Building
655 West Baltimore Street, Baltimore, Maryland 21201 (301) 328-2304

IVF/GIFT SURVEY

CLINIC NAME: Women's Hospital Fertility Center & IVF Program
ADDRESS: Greater Baltimore Medical Center
6701 N. Charles St.
Baltimore, MD 21204
Jairo Garcia, M.D., Director
CONTACT PERSON: Mrs. Linda Lynch, IVF Coordinator
PHONE NUMBER: (301) 828-2484

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 9/30/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? Two

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? Two, plus one eligible

6. How many other professionals participate in your clinic?
   - (a) Physicians 1
   - (b) Laboratory Scientists (PhDs) ________
   - (c) Nurses 4
   - (d) Embryo Lab Technicians/Technologists 6
   - (e) Other Lab Technicians/Technologists 5
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 4
   - (i) Other (specify) 1 Clin. Coordinator

7. How many years has your infertility clinic been in operation? 4 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF Sept/84 GIFT April/86

9. How many different patients were stimulated?
1987 IVF 280 1988 IVF 241
GIFT 19 GIFT 32

10. How many stimulation cycles were performed?
1987 IVF 440 1988 IVF 354
GIFT 23 GIFT 36

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 440 1988 354

How many embryo transfer cycles were performed?
1987 386 1988 328

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 23 1988 36

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 152 54.2% 1988 IVF 122 50.6%
GIFT 0 - % GIFT 0 - %
(b) Endometriosis:
1987 IVF 69 24.6% 1988 IVF 64 26.5%
GIFT 9 47.3 % GIFT 18 56.25 %
(c) Male infertility:
1987 IVF 39 14 % 1988 IVF 39 16.1%
GIFT 4 21.0 % GIFT 7 21.8 %
(d) Unexplained infertility:
1987 IVF 12 4.2% 1988 IVF 8 3.3%
GIFT 4 21.0 % GIFT 6 18.7 %
(e) Other (explain): PCO with multiple ovulation inductions & no pregnancies
1987 IVF 8 2.8% 1988 IVF 5 2.0 %
GIFT 2 10.5 % GIFT 1 3.1 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 61 21.7% 1988 IVF 56 23.3%
GIFT 6 31.5 % GIFT 6 18.7 %
(b) 31-35:
1987 IVF 105 37.5% 1988 IVF 88 36.5%
GIFT 7 36.8 % GIFT 15 46.8 %
(c) 36-40:
1987 IVF 95 33.9% 1988 IVF 84 34.8%
GIFT 5 26.3 % GIFT 6 18.7 %

(d) 41-45:
1987 IVF 19 6.7 % 1988 IVF 13 5.4 %
GIFT 1 5.2 % GIFT 5 15.6 %

(e) >45:
1987 IVF 0 - % 1988 IVF 0 - %
GIFT 0 - % GIFT 0 - %

16. How many clinical pregnancies were produced?
1987 IVF 98 1988 IVF 107
GIFT 3 GIFT 9

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 61 1988 IVF 24
GIFT 3 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 48
GIFT 0 GIFT 6

19. How many ectopic pregnancies resulted?
1987 IVF 3* 1988 IVF 2 *1 intrauterine - term
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 61 95 % 50 single; 11 twins
GIFT 3 5 % 2 single; 1 twin

Delivered and ongoing pregnancies 1988 IVF 72 91 % 50 single; 14 twins; 8 triplets; 1 quadruplet
GIFT 7 9 % 1 twins delivered; 5 single; 1 twins - ongoing

All ongoing > 12 weeks, positive heart beats by ultrasound

21. What are the qualifications of the director of the embryo laboratory? Board certified clinical-anatomic pathologist with 25 years experience

22. Who supervises the laboratory director? Advisory Committee to the IVF Program/Fertility Center

23. Does the clinic participate in an external laboratory proficiency testing program? No*
If the answer is yes, please specify which program.
*Not aware of any applicable program. The lab is accredited by CAP

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** Yes

27. **Does the clinic train individuals in IVF or GIFT?** No
If the answer is yes, how many individuals in the following specialties have been trained?
   (a) Physicians ________
   (b) Laboratory scientists (PhDs) _______
   (c) Embryo laboratory technicians/technologists _____
   (d) Nurses _______
   (e) Other (explain) ________

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

The success of our program is due to a dedicated team effort at both the laboratory and clinical levels. Control of ovulation is as critical as the classification of oocytes. The hormones used in every patient are tailored for each patient on an individual basis, according to patient response, rather than a fixed regime.

Due to the success of the program, there is currently a six month's waiting list for entrance into our program.

The State of Maryland is the leader in the country in passing a law requiring insurance companies to honor coverage of the IVF procedure for its residents.

Mark Balkin

IVF/GIFT SURVEY

CLINIC NAME: Johns Hopkins In Vitro Fertilization Program
ADDRESS: Johns Hopkins Hospital
Baltimore, Md. 21205

CONTACT PERSON: Dr. Marian Damewood
PHONE NUMBER: (301) 955-2016

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the never clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 5 - board certified 4 - fellows

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
   - (a) Physicians ______
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 2
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 4½

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1984 GIFT 1986

Mark Balkin

9. How many different patients were stimulated?
1987 IVF 50 1988 IVF 68
GIFT 4 GIFT 8

10. How many stimulation cycles were performed?
1987 IVF 81 1988 IVF 96
GIFT 4 GIFT 8

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 59 1988 76

How many embryo transfer cycles were performed?
1987 45 1988 67

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 4 1988 8

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ~~26~~ 25% 1988 IVF ___ 27%
GIFT ___ —% GIFT ___ —%
(b) Endometriosis:
1987 IVF ___ 23% 1988 IVF ___ 29%
GIFT ___ 30% GIFT ___ 42%
(c) Male infertility:
1987 IVF ___ 10% 1988 IVF ___ 16%
GIFT ___ —% GIFT ___ —%
(d) Unexplained infertility:
1987 IVF ___ 20% 1988 IVF ___ 15%
GIFT ___ 70% GIFT ___ 58%
(e) Other (explain): Immunologic
1987 IVF ___ 22% 1988 IVF ___ 11%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ 14% 1988 IVF ___ 18%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ 27% 1988 IVF ___ 21%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ 59% 1988 IVF ___ 61%
GIFT ___ ___% GIFT ___ ___%

Mark Belkin

(d) 41-45:
1987 IVF — —% 1988 IVF — —%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF — —% 1988 IVF — —%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

Many patients fro... out of the country data not complete here

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ 29 % ____________
GIFT ___ 37 % ____________

1988 IVF ___ 23 % ____________
GIFT ___ 29 % ____________

21. What are the qualifications of the director of the embryo laboratory? Experience with embryo · animal models Ph.D. or Master's degree in related field

22. Who supervises the laboratory director? Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? ____________
If the answer is yes, please specify which program.
Quality Control Assays for media done in another laboratory at Johns Hopkins

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

Mark Baker

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 6-8
    (b) Laboratory scientists (PhDs) 1
    (c) Embryo laboratory technicians/technologists 3
    (d) Nurses 2
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Patient population with multiple infertility problems present in one patient or couple.

Very commonly a couple with have endometriosis or tubal factor infertility along with a male factor.

IVF/GIFT SURVEY

CLINIC NAME: Center for Reproductive Studies and Infertility
ADDRESS: The Union Memorial Hospital
201 East University Parkway
Baltimore, MD 21218

CONTACT PERSON: Patricia Matkins- Patient Coordinator
PHONE NUMBER: 301-554-2942

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based X
   (c) University based ______
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 0

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   (a) Physicians 2
   (b) Laboratory Scientists (PhDs) ______
   (c) Nurses ______
   (d) Embryo Lab Technicians/Technologists 1
   (e) Other Lab Technicians/Technologists ______
   (f) Radiology (Ultrasound) Technicians ______
   (g) Psychologists/Counselors ______
   (h) Secretaries 2
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 5 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1987

9. How many different patients were stimulated?
1987 IVF 34 1988 IVF 34
GIFT 3 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 94 1988 IVF 80
GIFT 3 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 75 1988 62

How many embryo transfer cycles were performed?
1987 44 1988 54

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 3 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0% 1988 0 0%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 31 86% 1988 IVF 30 86%
GIFT 0 0% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 7 22% 1988 IVF 10 28%
GIFT 2 5.4% GIFT ___ ___%

Most of our patients have multiple problems.

(c) Male infertility:
1987 IVF 15 48% 1988 IVF 10 28%
GIFT 0 0% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF 1 2.7% 1988 IVF 1 2.8%
GIFT 1 2.7% GIFT 1 2.8%
(e) Other (explain): No uterus-embryos to surrogate/ DES
1987 IVF 2 5.4% 1988 IVF 3 8.5%
GIFT 0 0% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 5 13.5% 1988 IVF 5 14.2%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF 18 49% 1988 IVF 18 51%
GIFT 2 5.4% GIFT ___ ___%
(c) 36-40:
1987 IVF 7 18.9% 1988 IVF 7 20%
GIFT 1 2.7% GIFT 1 2.8%

(d) 41-45:
1987 IVF 4 10.8% 1988 IVF 4 11.4%
GIFT 0 0 % GIFT ___ ___%
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 4 1988 IVF 9
GIFT 2 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 1 1988 IVF 5
GIFT 1 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 2
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 1 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 100% Twins
GIFT 0 0 %

1988 IVF 1 20 % Twins (one additional triplet pregnancy in process)
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? An individual with knowledge of, and practical experience in Tissue Culture, gamete maturation, fertilization and early zygote cleavage in human and animal systems. Also having competence in semenology.

22. Who supervises the laboratory director? The Medical Director

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    - (a) Physicians ______
    - (b) Laboratory scientists (PhDs) ______
    - (c) Embryo laboratory technicians/technologists ______
    - (d) Nurses ______
    - (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Our program has a low volume of patients by choice. Each candidate receives indivualized attention and an IVF cycle is attempted based on her individual cycle, as opposed to a group approach.

Sen Wyden

IVF/GIFT SURVEY

CLINIC NAME: Montgomery Infertility Institute
ADDRESS: 10215 Fernwood Road Suite 303
Bethesda, Maryland 20817

CONTACT PERSON: Barbara Martin, R.N.
PHONE NUMBER: 301-897-8850

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 1-1-89

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private X
   (b) Community hospital based ________
   (c) University based ________
   (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   (a) Physicians 3
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 5
   (d) Embryo Lab Technicians/Technologists ________
   (e) Other Lab Technicians/Technologists 2
   (f) Radiology (Ultrasound) Technicians 2
   (g) Psychologists/Counselors 1
   (h) Secretaries 3
   (i) Other (specify) Business Office - 2
   Physicians (Boara Certified OB/GYN not practicing
7. How many years has your infertility clinic been in Infertility 3)
operation? 2½

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 5-86 GIFT 5-86

Same pt. twice in one year

9. How many different patients were stimulated?
1987 IVF 39 1988 IVF ~~52~~ 57
GIFT 13 GIFT 40

10. How many stimulation cycles were performed?
1987 IVF 46 1988 IVF 68
GIFT 14 GIFT 48

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 47 1988 68

How many embryo transfer cycles were performed?
1987 43 1988 62

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 14 1988 48

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0 % 1988 ___ 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
IVF/GIFT 2 20% 1987 IVF 9 30 % 1988 IVF 9 27%
GIFT 0 0 % GIFT 2 13 % IVF/GIFT 5 21%
(b) Endometriosis:
IVF/GIFT 3 30% 1987 IVF 3 10 % 1988 IVF 5 15 %
GIFT 0 0 % GIFT 5 31 % IVF/GIFT 2 8%
(c) Male infertility:
IVF/GIFT 1 10% 1987 IVF 4 13 % 1988 IVF 10 30 %
GIFT 1 33 % GIFT 3 18 % IVF/GIFT 8 33%
(d) Unexplained infertility:
IVF/GIFT 3 30% 1987 IVF 5 17 % 1988 IVF 16 48 %
GIFT 0 0 % GIFT 9 56 % IVF/GIFT 17 70%
(e) Other (explain): ____________
IVF/GIFT 2 20% 1987 IVF 11 37 % 1988 IVF 12 36 %
GIFT 3 100% GIFT 6 37 % IVF/GIFT 5 20%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 3 10 % 1988 IVF 4 12 %
IVF/GIFT 1 10% GIFT 0 0 % GIFT 2 12 % IVF/GIFT 3 12%
(b) 31-35:
IVF/GIFT 3 30% 1987 IVF 15 50 % 1988 IVF 13 39 %
GIFT 2 66 % GIFT 6 37 % IVF/GIFT 9 37%
(c) 36-40:
IVF/GIFT 6 60% 1987 IVF 7 23 % 1988 IVF 13 39 %
GIFT 1 33 % GIFT 5 31 % IVF/GIFT 11 46%

(d) 41-45:
1987 IVF 5 17 % 1988 IVF 3 9 %
GIFT 0 0 % GIFT 3 19 % IVF/GIFT 1 4%
(e) >45:
1987 IVF 0 17% 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 5 1988 IVF 6
GIFT 3 GIFT 9

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 5 1988 IVF 2
GIFT 2 GIFT 4

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 3
GIFT 0 GIFT 5

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 1 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 % ____________
GIFT 0 0 % ____________

1988 IVF 0 0 % ____________
GIFT 1 33 % 1 set twins

21. What are the qualifications of the director of the embryo laboratory? Dr. Ken Lipetz has a Ph.D. in Reproductive Physiology, specializing in Embryology and Gamete Physiology. Six years experience in embryo culture and early embryo survival.

22. Who supervises the laboratory director? Jay M. Grodin, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? yes
If the answer is yes, please specify which program.
College of American Pathologist-Excell Program for Laboratories.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** Yes and certified by SART

27. **Does the clinic train individuals in IVF or GIFT?** no
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) **Physicians** ________
    (b) **Laboratory scientists (PhDs)** ________
    (c) **Embryo laboratory technicians/technologists** ______
    (d) **Nurses** ________
    (e) **Other (explain)** ________

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

The majority of the patients at MII are from physician referral and represent patients with long-term infertility problems and subsequently are harder to treat. The average age of our patients in the IVF program is 37.5 years. The Institute has three board-certified Reproductive Endocrinologists and a Reproductive Physiologist with over 20 years of continuous experience specializing in the evaluation and treatment of infertile couple. We are unique in being the only private group to provide this wide range of services in the Washington Metropolitan area. MII also has a fully accredited clinical laboratory with facilities for endocrine studies, ovum/embryo cryo preservation and andrology capabilities.

IVF/GIFT SURVEY

CLINIC NAME: BRIGHAM AND WOMEN'S HOSPITAL
ADDRESS: 75 FRANCIS STREET
BOSTON, MASS 02115
ATTN: BRIGHAM IVF PROGRAM

CONTACT PERSON: DR. VERONICA RAVNIKAR
PHONE NUMBER: MEDICAL DIRECTOR

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private
   - (b) Community hospital based
   - (c) University based X AFFILIATION WITH HARVARD MEDICAL SCHOOL
   - (d) Other (explain)

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2 BOARD CERTIFIED
2 BOARD ELIGIBLE

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3 BOARD CERTIFIED
1 BOARD ELIGIBLE

6. How many other professionals participate in your clinic?
   - (a) Physicians 3 - expanding as of 7/89 to ⑤
   - (b) Laboratory Scientists (PhDs) 2 PH.D'S., 1 M.D., 1 D.V.M.
   - (c) Nurses 3
   - (d) Embryo Lab Technicians/Technologists 1 B.S.
   - (e) Other Lab Technicians/Technologists 3 (REPR ENDO LAB)
   - (f) Radiology (Ultrasound) Technicians 4
   - (g) Psychologists/Counselors 2
   - (h) Secretaries 4
   - (i) Other (specify)

7. How many years has your infertility clinic been in operation? SINCE 1940

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 Clomid / Pergonal
GIFT 1986 Clomid / Pergonal

9. How many different patients were stimulated?
1987 IVF 81 1988 IVF 125
GIFT 8 GIFT 8

10. How many stimulation cycles were performed?
1987 IVF 94 1988 IVF 131
GIFT 9 GIFT 9

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 65 1988 73

How many embryo transfer cycles were performed?
1987 55 1988 55

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 8 1988 8

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0 % 1988 ___ 0 %

14. What were the number and percentage of patients treated for:

WE HAVE THIS INFORMATION ON FILE BUT NOT DISCRETELY LISTED UNDER ONE DIAGNOSIS

(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ____________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 10 12% 1988 IVF 12 10%
GIFT 0 ___% GIFT 1 12.5%
(b) 31-35:
1987 IVF 23 29% 1988 IVF 52 42%
GIFT 3 ___% GIFT 4 50%
(c) 36-40:
1987 IVF 36 44% 1988 IVF 47 37%
GIFT 3 ___% GIFT 1 12.5%

(d) 41-45:
1987 IVF 12 15% 1988 IVF 15 1 %
GIFT 2 ___% GIFT 2 25 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 ___%
GIFT 0 0 % GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF 14 1988 IVF 12
GIFT 2 GIFT 2

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 12 1988 IVF ___
GIFT 1 GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 8
GIFT 0 delivered GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 2 1988 IVF 2
GIFT 1 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ___
GIFT ___ ___% ___

1988 IVF ___ ___% ___
GIFT ___ ___% ___

21. What are the qualifications of the director of the embryo laboratory? Ph.D., ASSOCIATE PROFESSOR OF OBSTETRICS AND GYNECOLOGY AND REPRODUCTIVE BIOLOGY; twelve years experience in embryo culture

22. Who supervises the laboratory director? DR. KENNETH J. RYAN – DEPARTMENT CHAIRPERSON AND DR. VERONICA RAVNIKAR MEDICAL DIRECTOR

23. Does the clinic participate in an external laboratory proficiency testing program? NO; QUALITY CONTROL DONE WEEKLY BY LAB DIRECTOR
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? YES

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? YES

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 24
    (b) Laboratory scientists (PhDs) 5
    (c) Embryo laboratory technicians/technologists 2
    (d) Nurses 6
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The Brigham and Women's Hospital IVF Unit is a university-based program with Harvard Medical School. There are three full-time staff members who have appointments at bothe the hospital and the medical school: Dr. Veronica Ravnikar, Dr. Mark Hornstein, and Dr. Charlotte Richards. They in turn supervise six fellows during a two-year period. The embryologists are also members of the Medical School staff. All procedures are reviewed on a weekly basis in open conference. Only individuals felt to complete a mandated work-up are allowed to enter the cycle. The team has worked with local insurance companies in developing a standardized system for evaluating patients. The social workers are mandated to see each patient and assess patient's comprehension and fitness to undergo the IVF process. After the procedure is completed, a cycle review conference is held to evaluate patient's response and recommendation are made for a subsequent cycle. Quality Control is done by the Embryology staff.

Veronica Ravnikar
Veronica A. Ravnikar
Director, In Vitro Fertilization

BRIGHAM
AND
WOMEN'S
HOSPITAL

Department of Obstetrics & Gynecology
75 Francis Street, ASBI-3-073
Boston, Massachusetts 02115

(617) 732-5444

February 17, 1989

The Honorable Ron Wyden
c/o D. Ann Murphy
Subcommittee on Regulation and Business Opportunities
B-363 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Wyden:

Upon further clarification of the questions being asked in the IVF/GIFT survey, we would like to revise our answers to two of the questions:

Question 17: How many women delivered live infants from IVF/GIFT?

1987	IVF	2	1988	IVF	14
	GIFT	1		GIFT	0

Question 20: What were the number, percentage of all births, and plurality of multiple births?

1987	IVF	0	0%	
	GIFT	0	0%	
1988	IVF	3%	21%	2 twins and 1 set of triplets
	GIFT	0%	0%	

If you have any questions about these changes, please call me at (617) 732-5444.

Sincerely,

Emme Deland

Emme Deland
Administrator of Ob/Gyn

ED/dh
ED/Feb89L

A Teaching Affiliate of Harvard Medical School

IVF/GIFT SURVEY

RECEIVED
DEC 14 1988
Hon Ron Wyden

CLINIC NAME: DEPT. OB/GYN - IVF clinic
ADDRESS: New England medical center
750 Washington St. Box 36
Boston, MA 02111

CONTACT PERSON: STEVEN BAYER MD
PHONE NUMBER: (617) 956-6049

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 1/89

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians 4
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? ______

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 2/88 GIFT 2/88

9. How many different patients were stimulated?
1987 IVF — 1988 IVF 12
GIFT — GIFT one

10. How many stimulation cycles were performed?
1987 IVF — 1988 IVF 17
GIFT — GIFT one

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 — 1988 16

How many embryo transfer cycles were performed?
1987 — 1988 15

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 — 1988 one attempted

13. What were the number and percentage of patients on IRB approved research protocols?
1987 — % 1988 zero %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF — % 1988 IVF 4 30.7%
GIFT — % GIFT — %
(b) Endometriosis:
1987 IVF — % 1988 IVF 5 38.4%
GIFT — % GIFT — %
(c) Male infertility:
1987 IVF — % 1988 IVF 2 15.3%
GIFT — % GIFT — %
(d) Unexplained infertility:
1987 IVF — % 1988 IVF 2 15.3%
GIFT — % GIFT — %
(e) Other (explain): ________________
1987 IVF — % 1988 IVF ___ ___%
GIFT — % GIFT — %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF — % 1988 IVF 3 23 %
GIFT — % GIFT — %
(b) 31-35:
1987 IVF — % 1988 IVF 7 55 %
GIFT — % GIFT — %
(c) 36-40:
1987 IVF — % 1988 IVF 3 23 %
GIFT — % GIFT — %

(d) 41-45:
1987 IVF — % 1988 IVF Zero %
GIFT — % GIFT ___ ___ %

(e) >45:
1987 IVF ___ ___ % 1988 IVF ___ %
GIFT ___ ___ % GIFT Zero %

16. How many clinical pregnancies were produced?
1987 IVF — 1988 IVF 2
GIFT — GIFT —

17. How many women delivered live infants from IVF/GIFT?
1987 IVF — 1988 IVF 0
GIFT — GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF — 1988 IVF 2
GIFT — GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF — 1988 IVF 0
GIFT — GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF — % —
GIFT — % —

1988 IVF ___ ___ % ___
GIFT — % —

21. What are the qualifications of the director of the embryo laboratory? Ph. D in mammalian embryology

22. Who supervises the laboratory director? Director of IVF

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

RECEIVED
DEC 14 1988
Hon Ron Wyden

CLINIC NAME: DEPT. OB/Gyn - IVF clinic
ADDRESS: New England medical center
750 Washington St. Box 36
BOSTON, MA 02111

CONTACT PERSON: STEVEN BAYER MD
PHONE NUMBER: (617) 956-6049

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 1/89

2. Does your clinic perform IVF/GIFT treatments? yes
   (If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
   - (a) Physicians 4
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? ______

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 2/88 GIFT 7/88

9. How many different patients were stimulated?
1987 IVF ____ 1988 IVF 12
GIFT ____ GIFT one

10. How many stimulation cycles were performed?
1987 IVF ____ 1988 IVF 17
GIFT ____ GIFT one

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ____ 1988 16

How many embryo transfer cycles were performed?
1987 ____ 1988 15

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ____ 1988 one attempted

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ____ % 1988 zero %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ____ % 1988 IVF 4 30.7%
GIFT ____ % GIFT ____ %
(b) Endometriosis:
1987 IVF ____ % 1988 IVF 5 38.4%
GIFT ____ % GIFT ____ %
(c) Male infertility:
1987 IVF ____ % 1988 IVF 2 15.3%
GIFT ____ % GIFT ____ %
(d) Unexplained infertility:
1987 IVF ____ % 1988 IVF 2 15.3%
GIFT ____ % GIFT ____ %
(e) Other (explain): ____
1987 IVF ____ % 1988 IVF ____ %
GIFT ____ % GIFT ____ %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ____ % 1988 IVF 3 23 %
GIFT ____ % GIFT ____ %
(b) 31-35:
1987 IVF ____ % 1988 IVF 7 55 %
GIFT ____ % GIFT ____ %
(c) 36-40:
1987 IVF ____ % 1988 IVF 3 23 %
GIFT ____ % GIFT ____ %

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT Zero %

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT Zero %

16. How many clinical pregnancies were produced?
1987 IVF ___ 1988 IVF 2
GIFT ___ GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF 0
GIFT ___ GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 2
GIFT ___ GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF 0
GIFT ___ GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ___________
GIFT ___ ___% ___________

1988 IVF ___ ___% ___________
GIFT ___ ___% ___________

21. What are the qualifications of the director of the embryo laboratory? Ph. D in mammalian embryology

22. Who supervises the laboratory director? Director of IVF

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Boston IVF
ADDRESS: 1 Brookline Place Suite 602
Brookline, MA.
02146

CONTACT PERSON: Caroline Vosburgh/ Rhonda Steinberg-- Coordinators
PHONE NUMBER: (617) 735-9000 xt. 202

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based _____
   - (c) University based _____
   - (d) Other (explain) _____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 4

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
   - (a) Physicians 1
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 3
   - (d) Embryo Lab Technicians/Technologists 4
   - (e) Other Lab Technicians/Technologists _____
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 3
   - (i) Other (specify) _____

7. How many years has your infertility clinic been in operation? 2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 11/87 GIFT 11/87

9. How many different patients were stimulated?
1987 IVF 66 1988 IVF 257
GIFT 162 GIFT 280

10. How many stimulation cycles were performed?
1987 IVF 93 1988 IVF 333
GIFT 222 GIFT 342

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 61 1988 294

How many embryo transfer cycles were performed?
1987 53 1988 211

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 147 1988 260

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 70 75 % 1988 IVF 213 64 %
GIFT 14 6 % GIFT 28 8 %
(b) Endometriosis:
1987 IVF 10 10 % 1988 IVF 63 19 %
GIFT 105 47 % GIFT 143 41.8%
(c) Male infertility:
1987 IVF 6 6.4% 1988 IVF 31 9.3 %
GIFT 32 14 % GIFT 60 17.5%
(d) Unexplained infertility:
1987 IVF 6 6.4 % 1988 IVF 6 2 %
GIFT 53 24 % GIFT 37 10.8%
(e) Other (explain): ______________
1987 IVF 1 1 % 1988 IVF 13 4 %
GIFT 18 8 % GIFT 56 16 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 23 25 % 1988 IVF 42 12.6%
GIFT 31 14 % GIFT 42 12.3%
(b) 31-35:
1987 IVF 33 35 % 1988 IVF 122 36.6%
GIFT 96 43 % GIFT 116 33.9%
(c) 36-40:
1987 IVF 29 31 % 1988 IVF 138 41 %
GIFT 73 33 % GIFT 109 32 %

(d) 41-45:
1987 IVF 8 8.6 % 1988 IVF 22 6.6 %
GIFT 22 9.9% GIFT 67 19.6%

(e) >45:
1987 IVF 0 0 % 1988 IVF 4 1.2 %
GIFT 0 0 % GIFT 5 1.5 %

16. How many clinical pregnancies were produced?
1987 IVF 5 1988 IVF 30
GIFT 42 GIFT 60

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 3 1988 IVF 4
GIFT 27 GIFT 15

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 16
GIFT 0 GIFT 33

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 0
GIFT 1 GIFT 4

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 33 % 1tw healthy
GIFT 9 33 % 8tw. 1trip. healthy

1988 IVF 1 25 % 1tw. healthy ongoing : 1tw.
GIFT 3 20 % 2tw. 1quad. healthy ongoing: 9tw. 2trip.

21. What are the qualifications of the director of the embryo laboratory? PHd. Biology -- R. Douglas Powers

22. Who supervises the laboratory director? Irwin E. Thompson, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? PENDING

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 1-2
    (b) Laboratory scientists (PhDs) 1-2
    (c) Embryo laboratory technicians/technologists 1-2
    (d) Nurses 5-10
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Our program doe not exclude patients for age factor (patients over 40 are accepted) or male factor, which is reflected in our overall success rates.

IVF/GIFT SURVEY

CLINIC NAME: Beth Israel Hospital IVF/GIFT Program
ADDRESS: 330 Brookline Avenue
Boston, MA 02215

CONTACT PERSON: Machelle M. Seibel, M.D.
PHONE NUMBER: (617) 735-5923

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12-31-88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based XX
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified ~~and/or Board Eligible~~ Reproductive Endocrinologists participate in your clinic? 1 at present for past year

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? ______

6. How many other professionals participate in your clinic?
   - (a) Physicians 0 (1 other as of 7/89)
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 3
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 2
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 5 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 11/83 GIFT 1985

9. How many different patients were stimulated?
1987 IVF 126 1988 IVF 190
GIFT 13 GIFT 8

10. How many stimulation cycles were performed?
1987 IVF 223 1988 IVF 291
GIFT 17 GIFT 10

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 147 1988 183

How many embryo transfer cycles were performed?
1987 106 1988 156

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 10 1988 4

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

IVF/GIFT and all of the associated procedures are considered IRB approved protocols

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 93 73.8% 1988 IVF 125 65.8%
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 19 15.1% 1988 IVF 29 15.3%
GIFT 4 30.8 % GIFT 3 30.0 %
(c) Male infertility:
1987 IVF 10 7.9% 1988 IVF 29 15.3%
GIFT 3 23.1 % GIFT 2 20.0 %
(d) Unexplained infertility:
1987 IVF 12 9.5% 1988 IVF 23 12.1%
GIFT 5 38.5% GIFT 4 40 %
(e) Other (explain): GIFT; cervical; IVF: immune factor
1987 IVF 3 2.3% 1988 IVF 7 3.6 %
GIFT 1 7.7 % GIFT 1 10 %

Percentages add up to greater than 100% because several patients had more than one diagnosis(percentages were calculated out of total number of patients treated).

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 15 11.9% 1988 IVF 28 14.7%
GIFT 3 23.1% GIFT 1 12.5%
(b) 31-35:
1987 IVF 51 40.5% 1988 IVF 72 37.9%
GIFT 7 53.8% GIFT 2 25 %
(c) 36-40:
1987 IVF 45 35.7% 1988 IVF 68 35.8%
GIFT 2 15.4% GIFT 2 25 %

(d) 41-45:
1987 IVF 14 11.1% 1988 IVF 20 10.5%
GIFT 1 7.7% GIFT 2 25 %
(e) >45:
1987 IVF 1 0.8 % 1988 IVF 2 1.1%
GIFT 0 0 % GIFT 1 12.5%

16. How many clinical pregnancies were produced?
1987 IVF 11 1988 IVF 14
GIFT 1 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 8 1988 IVF 9
GIFT 1 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF N/A 1988 IVF 10
GIFT N/A GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 22.2% one set of twins
GIFT 2 100 % one set of twins

1988 IVF 2 20% one set of twins
GIFT ___ ___%

21. What are the qualifications of the director of the embryo laboratory? 5 years performing IVF, MD/PhD

22. Who supervises the laboratory director? weekly team meetings with Medical Director

23. Does the clinic participate in an external laboratory proficiency testing program?
If the answer is yes, please specify which program.
RIA component

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** yes

27. **Does the clinic train individuals in IVF or GIFT?** yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) **Physicians** 20
    (b) **Laboratory scientists (PhDs)** 20
    (c) **Embryo laboratory technicians/technologists** _____
    (d) **Nurses** _____
    (e) **Other (explain)** one week workshops annually

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

This questionaire is worrisome because of several reasons. You have no proof of accuracy. Also, we have a very old population with many patients over 40. We have no restrictions on sperm count or combined problems. If we are compared with centers who have many restrictions and who do not report their data totally accurately, it makes an honest center look bad. I cannot see how this questionaire resolves the intended purpose as people may not report their results to you any differently that they do to anyone else.

P.S. Please see attached article.

After Office Hours

IN VITRO FERTILIZATION SUCCESS RATES: A FRACTION OF THE TRUTH

Machelle M. Seibel, MD

A couple recently came into my office and the wife asked me, "Doctor, we are looking for the best IVF [in vitro fertilization] program. What is your success rate?" I responded, of course, that I would be happy to answer that question. But deep down I knew it would not be a simple response. "I want to tell you the whole truth," I responded. "What do you mean," she replied, "doesn't every IVF program tell the whole truth?" I realized immediately that my answer could be misconstrued. "I am confident," I said, "that doctors and IVF team members do not lie. The problem is mathematical." "Mathematical?" she replied. "Mathematical," I confirmed, and proceeded to explain about a fraction of the truth. "You see, every fraction has a numerator and a denominator. In IVF the numerator is the number of pregnancies." This was so obvious to my patient that she became indignant. "Babies are the numerator," she quipped. "They certainly may be," I agreed. "But the numerator is pregnancies. All pregnancies do not result in babies in a fraction of the truth."

With some hesitation I struggled to explain. "The numerator may represent a positive pregnancy test or a term pregnancy." "I'm beginning to understand," she responded. Her girlfriend had recently conceived by IVF. They had even seen the fetus on ultrasound and called it a clinical pregnancy. It was ongoing for another month. Unfortunately, her friend had a miscarriage a few weeks later. I responded, "I am sorry to hear that, but according to the mathematics of a fraction of the truth, she can still be counted as a pregnancy."

I continued my discussion of a fraction of the truth by talking about the denominator. "The denominator," I said, "is even more confusing to explain. It can represent patients, oocyte retrievals, or embryo transfers." "Can you give me an example to illustrate your point?" she interjected. "I am having trouble understanding the denominator." I never liked math, I mused to myself, but a theoretical model might just do the trick. "Let's pretend a new IVF clinic has one patient who goes through the procedure five times. The first time, they fail to retrieve an egg, and the second time, the retrieved eggs fail to fertilize. The last three cycles result in embryo transfers and the patient conceives on her fifth attempt. What is the success rate?" After some consideration, the patient responded, "The IVF success rate is one pregnancy per five oocyte retrievals or 20%, one pregnancy per three embryo transfers or 33%, or one pregnancy per one patient or 100%, depending on which denominator you choose." "That's right!" I told her, "but don't forget about the numerator in a fraction of the truth."

At this point the husband, who had been largely silent, spoke up for the first time, close to tears. "My sperm count is low," he confessed. "If IVF success rates are only reported as pregnancy per embryo transfer, then all of the procedures in which fertilization does not occur will not be included. Won't that make the results seem higher?" "That's correct," I agreed. "Omitting the failed fertilizations make the results seem higher, even though a fraction of the truth is reported correctly."

At this time our interview was drawing to a close. "Are there any other important points about a fraction of the truth?" the wife inquired. "There are two mathematical variables that must also be considered in a fraction of the truth," I responded. "They are time and patient selection. You see, if IVF success rates represent only a particularly successful interval of time, the results will seem higher. Results will also seem increased if they exclude older patients or men whose sperm counts are extremely low," I explained.

From the Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, Dana Biomedical Research Laboratories, Beth Israel Hospital and Harvard Medical School, Boston, Massachusetts.

"One of my friends has tried many times unsuccessfully to achieve an IVF pregnancy," the wife admitted. "I guess couples like them make the results seem lower too." "Absolutely," I responded, "but couples with a poor chance of success want a baby so badly that IVF centers differ in opinion about these kinds of issues."

"What is the whole truth?" the couple asked together. For the question they had initially asked had still not been answered. I responded cautiously. The answer they wanted was still not simple. "If one considers all patients, regardless of age or medical problems, the expected term pregnancy rate per oocyte retrieval is approximately ten to fifteen percent at better centers." "And what about centers that claim to have success rates that are so much higher?" the wife blurted out in disbelief. She had expected results that were really much better. "It's possible," I responded, "but be sure you determine whether the results are the whole truth, or a fraction of the truth."

Address reprint requests to:
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Department of Obstetrics and Gynecology
Beth Israel Hospital
330 Brookline Avenue
Boston, MA 02215

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IVF/GIFT SURVEY

CLINIC NAME: AtlantiCare Fertility Center
ADDRESS: 500 Lynnfield Street
Lynn, MA 01904

CONTACT PERSON: Dr. V. Cardone/Nancy Harrington, R.N.
PHONE NUMBER: 617-581-0330

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Dec 31, 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private _______
   - (b) Community hospital based _______
   - (c) University based _______
   - (d) Other (explain) Private Hospital

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? Equivalent of 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? One

6. How many other professionals participate in your clinic?
   - (a) Physicians N.A.
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 6
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 0
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 1 - on demand
   - (h) Secretaries 1
   - (i) Other (specify) 1 Business Manager

7. How many years has your infertility clinic been in operation? Since Feb 27, 1988

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF Feb 27, 1988 GIFT _______

9. How many different patients were stimulated?
1987 IVF ___ 1988 IVF 71
GIFT ___ GIFT 0

10. How many stimulation cycles were performed?
1987 IVF ___ 1988 IVF 103
GIFT ___ GIFT 0

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ___ 1988 94

How many embryo transfer cycles were performed?
1987 ___ 1988 66

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ___ 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 0 0%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF 40 58%
GIFT ___ ___% GIFT 0 0 %
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 10 14 %
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 3 4 %
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF 7 10 %
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): See Additional
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF 15 21%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF 42 59%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF 11 15%
GIFT ___ ___% GIFT ___ ___%

14e Other

1988 Male infertility and tubal factor = 1 1%

Endometriosis and tubal = 5 7%

No ovaries = 1 1%

Endometriosis and no ovaries = 1 1%

Endometriosis and male infertility = 2 3%

An ovulatory = 1 1%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF 1 4%
GIFT ___ ___% GIFT ___ ___%
(e) >45:
1987 IVF ___ ___% 1988 IVF 0 0%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF ___ 1988 IVF 13
GIFT ___ GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF 1
GIFT ___ GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 8
GIFT ___ GIFT ___

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF 1
GIFT ___ GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ___
GIFT ___ ___% ___

1988 IVF ___ ___% ___
GIFT ___ ___% ___

21. What are the qualifications of the director of the embryo laboratory? PhD. in Physiology

22. Who supervises the laboratory director? Medical Director, Dr. Cardone

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** Pending the number of deliveries.

27. **Does the clinic train individuals in IVF or GIFT?** Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    - **(a) Physicians** ________
    - **(b) Laboratory scientists (PhDs)** 1
    - **(c) Embryo laboratory technicians/technologists** 1
    - **(d) Nurses** 6
    - **(e) Other (explain)** ________

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

Please excuse our delay in answering your questionnaire but our clinic has only been in operation since February 27, 1988 and we wanted to include the last group results. I would like to stress the set up and organization period did not produce as many pregnancies. However, in our program the last group done which consisted of 22 patients gave the following results.

3rd CYCLE STATISTICS

Number of patients stimulated per cycle	22
Number of patients cancelled before puncture	1
Number of patient egg(s) retrieved	21
Number of patients with embryo transfers	14
Number of pregnancies per puncture (%)	6 (29%)
Number of pregnancies per embryo transfer (%)	6 (43%)

IVF Australia Program–Boston

Waltham/Weston Hospital & Medical Center
Hope Avenue
Waltham, MA 02254
(617) 288-4812

February 14, 1989

Congressman Ron Wyden
B363 Rayburn House Office Building
Washington, DC 20515

Attn: Mark Belkin

Dear Congressman Wyden:

In reference to the survey which was sent to me regarding our IVF program results, I would like to advise you that our IVF program only recently began full operation. Our first egg retrieval began on February 6, 1989. I wanted to clarify that there are other IVF Australia Programs and each one will most likely be responding to your survey separately.

If there are any further questions which you may have, please do not hesitate to contact me. I wish you luck with your endeavor of informing the public about IVF program statistics.

Sincerely,

Patricia M. McShane, MD
Medical Director

PMM:jg

IVF/GIFT SURVEY

CLINIC NAME: Blodgett Memorial Medical Center, IVF Program
ADDRESS:
1900 Wealthy St., S. E.
Grand Rapids, Michigan 49506

CONTACT PERSON: Mary Hager, R.N.
PHONE NUMBER: 616-774-0700

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 31 December 1988

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians Radiologists and Anesthesiologists
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses Clinical Nurses - 2
   - (d) Embryo Lab Technicians/Technologists 4
   - (e) Other Lab Technicians/Technologists 4
   - (f) Radiology (Ultrasound) Technicians 4
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 2
   - (i) Other (specify) OR Nurses

7. How many years has your infertility clinic been in operation? Since 1963

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 31 July 1983 GIFT 13 February 1988

9. **How many different patients were stimulated?**
1987 IVF 37 1988 IVF 43
GIFT 0 GIFT 3

10. **How many stimulation cycles were performed?**
1987 IVF 43 1988 IVF 51
GIFT 0 GIFT 5

11. **For those clinics offering IVF:**
How many egg recovery procedures were performed?
1987 39 1988 44

How many embryo transfer cycles were performed?
1987 36 1988 40

12. **How many GIFT procedures (attempted egg recoveries) were performed?**
1987 0 1988 5

13. **What were the number and percentage of patients on IRB approved research protocols?**
1987 0 ___% 1988 0 ___%

14. **What were the number and percentage of patients treated for:**

Many patients have multiple infertility factors.

time constraints →

(a) **Tubal factor:**
1987 IVF ___ ___% 1988 IVF 36 ___%
GIFT ___ ___% GIFT ___ ___%
(b) **Endometriosis:**
1987 IVF ___ ___% 1988 IVF 2 ___%
GIFT ___ ___% GIFT ___ ___%
(c) **Male infertility:**
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) **Unexplained infertility:**
1987 IVF ___ ___% 1988 IVF 6 ___%
GIFT ___ ___% GIFT 3 ___%
(e) **Other (explain):** Immunological
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT 2 ___%

15. **What were the number and percentage of patients in the following age groups:**

— numbers chn.

(a) **<31:**
1987 IVF ___ ___% 1988 IVF 20 ___%
GIFT ___ ___% GIFT 2 ___%
(b) **31-35:**
1987 IVF ___ ___% 1988 IVF ~~17~~ 22 ___%
GIFT ___ ___% GIFT 3 ___%
(c) **36-40:**
1987 IVF ___ ___% 1988 IVF 9 ___%
GIFT ___ ___% GIFT 0 ___%

(d) 41-45:
1987 IVF -- --% 1988 IVF -- --%
GIFT -- --% GIFT -- --%

(e) >45:
1987 IVF -- --% 1988 IVF -- --%
GIFT -- --% GIFT -- --%

16. How many clinical pregnancies were produced?
1987 IVF 10 1988 IVF 10
GIFT NA GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 8 1988 IVF 8
GIFT NA GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 5
GIFT NA GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 1
GIFT NA GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 3 ___% twins
GIFT ___ ___%

1988 IVF 1 ___% twins
GIFT ___ ___%

21. What are the qualifications of the director of the embryo laboratory? PhD in Microbiology

22. Who supervises the laboratory director? Chairman, Dept. of Pathology
Blodgett Memorial Medical Center

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
College of American Pathologist/J.C.A.H.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ________
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

(see insert)

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In Vitro Fertilization in a Community Hospital

ROBERT D. VISSCHER, M.D., HAROLD A. MOORE, PH.D., AND MARY HAGER, R.N.

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Communications-in-Brief

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In vitro fertilization in a community hospital

Robert D. Visscher, M.D.*
Harold A. Moore, Ph.D.
Mary Hager, R.N.

Blodgett Memorial Medical Center, Grand Rapids, Michigan

Fifteen percent of all couples who desire to have children are faced with the frustrating problem of infertility. This situation presents a compelling challenge to those physicians, nurses, and technicians who are involved in reproductive medicine.

During the past 10 years, an explosive development of technology has taken place as better methods of treatment have been sought. A prime example is basic in vitro fertilization (IVF) and embryo transfer (ET), which has been refined sufficiently so that it is a well-established method for the treatment of various forms of infertility. It is now feasible to offer this service in the community hospital.

MATERIALS AND METHODS

PROGRAM DEVELOPMENT

Blodgett Memorial Medical Center in Grand Rapids, MI began the development of an IVF program in September 1982. The format was patterned after that of the Eastern Virginia Medical School in Norfolk, VA.[1-6]

This involved the establishment of animal and human IVF laboratories. The initial cost was $42,600 for equipment and $12,200 for space renovation.

It was also necessary to upgrade the andrology laboratory, ultrasound for follicular development, radioimmunoassay for estradiol (E_2) and luteinizing hormones, as well as surgery and anesthesia for follicular aspirations. Each of these areas was programmed to function 7 days a week.

All personnel involved with the project were recruited from within the hospital. A reproductive endocrinologist became the director of the program. A laboratory Ph.D. and four laboratory technicians from the microbiology division were selected to manage the andrology laboratory and the animal and IVF laboratories. A nurse practitioner was employed to coordinate all patient care functions.

The program became operational in August 1983.

ETHICAL STANDARDS

Because the ethical aspects of IVF are of concern to the team members, hospital personnel, patients, and the community in which the hospital is located, it was necessary to establish an ethical code of conduct that was acceptable to all concerned. The major elements of this code are as follows: (1) IVF-ET is a service provided for married couples; (2) sperm and ovum not used for insemination are given a scientific disposal like that of any surgical specimen; (3) it is assumed that human life begins with conception; because human life is sacred, and to be respected, all concepti (inseminated ova) are entitled to a continued existence in a life-supporting environment, either the human culture laboratory or the human uterus; and (4) it is agreed that there shall be no experimentation on embryos.

Received June 4, 1985; revised and accepted August 12, 1985.

*Reprint requests: Robert D. Visscher, M.D., Blodgett Memorial Medical Center, 1900 Wealthy, S.E., Grand Rapids, Michigan 49506.

PATIENT SELECTION

The couple, to be eligible for IVF, must have a long-standing problem with infertility that has not been resolved by more conventional therapy. The wife must be no more than 40 years of age. She must have at least one ovary that produces preovulatory follicles accessible at laparoscopy and a uterus capable of supporting a normal pregnancy. The husband must have sperm capable of fertilizing eggs.

Indications for IVF include one or more of the following conditions: (1) tubal factor: surgically absent tubes or nonfunctioning tubes that have failed tubal surgery or have severe fimbrial or cornual damage; (2) male factor: sperm counts with concentrations $< 20 \times 10^6$/ml, progressive motility $< 40\%$, or normal morphologic features $< 40\%$; (3) immune factor: antisperm antibodies in semen, cervical mucus, or serum of the husband or wife; (4) endometriosis: 1½ to 2 years beyond conventional medical and surgical therapy; and (5) unexplained infertility: negative workup and 4 to 5 years of infertility.

PATIENT WORKUP

Infertile couples who request IVF meet for consultation with the physician and the nurse practitioner. Their infertility history is reviewed in detail, and a decision as to their eligibility is made. Screening laparoscopies are not performed. An updated semen analysis is done. The couple is screened for infections, including *Ureaplasma urealyticum* and *Chlamydia trachomatis*.

There is a lengthy consent form, which is explained by the nurse practitioner and signed by each patient entering the program. The form covers the various steps in the procedure and the inherent risks and potential benefits.

Couples assigned to the waiting list for a treatment cycle usually have to wait 3 to 6 months. They are informed that the maximum cost per treatment cycle will be $4,000. However, the cost is usually in the range of $3,400 to $3,800.

TREATMENT CYCLE

Human menopausal gonadotropin (hMG) and human chorionic gonadotropin (hCG) are used for stimulation of folliculogenesis and ovum maturation. Injections are started at 4:00 P.M. on day 3 of the menstrual cycle, with the use of 3 ampules of hMG, unless a previous cycle showed the patient to be very sensitive to gonadotropin stimulation. Thereafter, 1 to 3 ampules of hMG are used every day, based on the E_2 level, follicular development on ultrasound, vaginal cytologic examination, and cervical mucus response. Gonadotropin stimulation is continued for 5 to 6 days to select several preovulatory follicles in each ovary. It is terminated when (1) there is a consistent rise in E_2 level for 4 days; (2) there are two or more follicles of ≥ 13 mm in diameter; and (3) there is a good vaginal wall karyopyknotic and cervical mucus response. Administration of hCG, 10,000 IU, is given 52 hours later, at 8:00 P.M. Follicular aspiration is carried out 36 hours later, at 8:00 A.M. Follicular aspiration and oocyte recovery are performed by laparoscopy, under general anesthesia, in the outpatient surgical area of the hospital. A double-lumen aspirator needle with foot suction is used for aspiration of the follicles. The follicular fluid is collected in phosphate-buffered saline and brought to the human IVF laboratory across the hall. Ideally, five to six oocytes are obtained, classified, and transferred to Ham's F-10 insemination culture media containing 7.5% fetal cord serum. After incubating the mature oocytes in 5% CO_2 and air for 5 or 6 hours, the oocytes are inseminated with 50,000 motile washed sperm/ml. After approximately 16 hours, the oocytes are evaluated for evidence of fertilization (two pronuclei) and transferred to growth media containing 15% fetal cord serum. About 24 hours later, the concepti are evaluated for evidence of cleavage. At this time, which is about 40 hours after insemination of the mature oocytes, the embryos are at the 4- to 8-cell stage.

One to 2 hours later, which is 42 hours after insemination of the mature oocytes or 48 hours after follicular aspiration, the concepti are transferred to the upper uterine cavity in growth media. A transfer catheter and cannula are used with the patient in the knee-chest position. Ideally, three to four embryos are transferred to the uterus. However, all inseminated oocytes are considered concepti and are transferred, unless they show evidence of degeneration. The concepti are classified as (1) embryos, two or more cells; (2) zygotes, two pronuclei; and (3) unclassified concepti, no evidence of fertilization. The patient is kept at bedrest in the patient holding area in outpatient surgery for 4 hours before being released from the hospital. She is on limited activ-

Table 1. *Treatment Cycles from August 1983 to March 1985*

Cancelled cycles	6
Laparoscopy cycles	58
Transfer cycles	47
Pregnancies	12
Pregnancies per laparoscopy cycle	21%
Pregnancies per transfer cycle	26%

ity for the next 24 hours, after which she is free to carry out her regular activities.

The luteal phase of the cycle is supported with progesterone, 12.5 mg/day intramuscularly. Blood tests for quantitative β-hCG are performed beginning 8 days after ET. If there is a significant titer and subsequent β-hCG titers at 2- to 3-day intervals show a doubling or more of the titer on two occasions, the patient is considered pregnant. Confirmation of pregnancy occurs about 1 week beyond the expected menstrual period. Chemical pregnancies are not included.[7] The pregnancy is evaluated by ultrasound at 5 to 6 weeks for gestational sacs and 7 to 8 weeks for viable embryos. The pregnant patient is referred back to her obstetrician for regular prenatal care at 8 weeks' gestation.

If the woman does not become pregnant, approximately 2 weeks after her menstrual period she and her husband come back for an exit consultation. The entire IVF cycle is reviewed, including the response to hMG, findings at laparoscopy, and outcome of every egg that was harvested at laparoscopy. We also discuss the quality of the semen, oocyte fertilization and cleavage, and the quality of the embryos developed based on morphologic criteria. If a reasonable number of oocytes were harvested and there was a good fertilization and cleavage rate, the couple is considered a candidate for a repeat cycle in 3 or more months, assuming that it is emotionally and financially feasible.

RESULTS*

From August 1983 through March 1985, 55 patients were treated. The treatment cycle (Table 1) was cancelled six times (9.4%) because of inadequate follicular development. Forty-nine patients went through 58 complete IVF laparoscopy cycles. The number of ampules of hMG used over the usual 5 to 6 days of stimulation ranged from 8 to 20, with an average of 13.2 ampules. Oocyte recovery per laparoscopy cycle ranged from 2 to 11, with an average of 5.2 oocytes. Based on the morphologic features of the cumulus-oocyte complex, 78% of the oocytes were considered mature, 6% intermediate, 15% immature, and 1% atretic. In 57 (98%) of the 58 laparoscopy cycles, at least one of the oocytes was fertilized. The fertilization rate per oocyte inseminated was 67%. Eighty percent of the inseminated oocytes that showed evidence of fertilization underwent cleavage. In 47 (81%) of the 58 laparoscopy cycles, the patients received one or more embryos. In the transfer cycles, the patients received from 1 to 6 embryos, with an average of 2.8 embryos.

The first pregnancy occurred after the eighth treatment cycle. The patient had a twin pregnancy, and two normal healthy girls were delivered on June 10, 1984. During this initial phase of the program, there have been 12 pregnancies in all (Table 2), including two sets of twins and one set of triplets. There has been one preclinical abortion and two clinical abortions.[7] In the nine repeat cycles, three patients achieved pregnancy. Eight normal healthy infants have been born to date. The pregnancy rate per laparoscopy cycle is 21% and per transfer cycle is 26%. Table 3 lists the indications for IVF and relates them to outcome. Table 4 relates outcome to the number of embryos transferred.

DISCUSSION

With any new technologic development, the medical practitioner has to determine whether there has been sufficient progress to make it practical to incorporate the new procedure into his or her practice. In regard to IVF, the question was whether it has been developed to the level where it is feasible to provide this service in a community hospital. We assessed that situation in 1982 by determining what were the necessary laboratory facilities and personnel requirements to conduct an IVF program. We also considered whether the anticipated results and costs would be at a reasonable level that was acceptable to our pa-

Table 2. *Pregnancies*

Total pregnancies	12
Preclinical abortions	1
Clinical abortions	2
Viable pregnancies	9
Twins	2
Triplets	1

---

*See Addendum.

Table 3. *Pregnancies Related to Indications for IVF*

Indications	Laparoscopy cycles	Transfer cycles	Pregnancies
Tubal	43	38	10
Endometriosis	4	3	1
Oligospermia	1	1	0
Antisperm antibodies	1	0	0
Unexplained infertility	9	5	1
Total	58	47	12

tients. There also was the challenge of defining an ethical code of conduct that was acceptable to all team members involved, the patients, and the community in which we live.

According to our evaluation, we thought it was possible to develop an IVF program at Blodgett Memorial Medical Center by modifying our present laboratory facilities, using in-house personnel, and doing it at a reasonable cost. Our goal was to develop a program that would have a pregnancy rate of 15% to 20% per laparoscopy cycle at a cost of $4,000 per cycle. The major ethical consideration was what status would be given to the conceptus. For our program, it is assumed that human life begins with conception. And as human life is sacred and to be respected, all concepti are entitled to a continued existence.

Based on our pregnancy rate of 21% per laparoscopy cycle, cost of less than $4,000 per cycle, and ethical standards acceptable to all concerned, we believe we have been successful in developing a basic IVF program to serve the needs of our patients. We attribute our success primarily to the expertise and dedication of all the team members. Doing about six to eight cases a month has maintained a good pace for focusing a lot of attention on each patient who undergoes a treatment cycle. That number has also allowed us to maintain good quality control and a cost-effective program.

The animal laboratory facility was a valuable asset in helping us initiate our program. In addition, it has allowed us to maintain good quality control of our ongoing program.

As a result of the basic IVF program, other services for infertile patients have been developed. Semen evaluation has been significantly improved. With the use of the culture media of the IVF program, intrauterine inseminations with washed sperm are now possible for couples whose infertility problem relates to abnormal cervical factor or oligospermia. Daily monitoring of E_2 and luteinizing hormone levels and follicular development seen by ultrasound allows more critical inductions of ovulation in those patients who do not respond to clomiphene citrate and hCG therapy. Other potential programs include ovum donation and oocyte and embryo freezing, assuming that the ethical, legal, and technical aspects can be developed. Indeed, it is very exciting to realize what can be done for infertile couples at present and project what services may be available to them in the future to fulfill their overwhelming desire to be parents.

SUMMARY

Blodgett Memorial Medical Center began developing an IVF program in September of 1982. It took 10 months to establish animal and human IVF laboratories and an andrology laboratory. All personnel were recruited from within the hospital.

From August 1983 through March 1985, 49 patients went through 58 complete IVF laparoscopy cycles. hMG and hCG were used to stimulate folliculogenesis and ovum maturation. An average of 5.2 oocytes was obtained by laparoscopic follicular aspiration. Eighty-four percent were either mature or intermediate oocytes. The fertilization rate per oocyte was 67%. Eighty percent underwent cleavage. Forty-seven patients (81%) received 1 or more embryos, with an average of 2.8 embryos each. There have been 12 pregnancies, including 3 abortions and 3 multiple pregnancies. Eight healthy infants have been born to date. The pregnancy rate per laparoscopy cycle was 21% and per transfer cycle was 26%.

As a result of the IVF program, other services for infertile couples have been developed.

Table 4. *Pregnancies Related to Number of Embryos Transferred*

No. of embryos transferred	Transfer cycles	Pregnancies	Comments
1	10	2	
2	15	2	
3	8	4	One set of twins
4	5	1	
5	6	3	One set of triplets One set of twins
6	3	0	
Total	47	12	

ADDENDUM

At the time of the final review of this manuscript in October 1985, 21 women have conceived as a result of our IVF program. This represents 23.3% of the 90 laparoscopy cycles and 28.8% of the 73 transfer cycles. Five women have aborted. Three have had multiple pregnancies. Eleven normal infants have been delivered.

This is an archival report, but is being published because it serves to point out that excellent pregnancy rates can be achieved in a small private IVF-ET program. The authors acknowledge that there is nothing unique in the methodology employed. It is closely modified after the Jones' Program.

The Editor

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Enclosed is a copy of an article in the December, 1985 Journal of Fertility and Sterility. The comments in that article on program development, ethical standards, patient selection and patient workup give a succinct overview of the history of our IVF Program and the standards of care. As mentioned, we started developing our IVF Program in September of 1982 and did our first IVF/ET 31 July 1983. Our first pregnancy occurred on our 8th treatment cycle and the patient delivered twins on 10 June 1984. Below are our overall statistics for every IVF and GIFT case that we did over a period of 5 years and 5 months from 31 July 1983 through 31 December 1988.

Total Cycles: 279

Cancelled Cycles: 37 (13%)

Total GIFT Cycles: 5

Total IVF/ET Cycles: 237

- Follicular aspiration
  - Laparoscopy: 201
  - Ultrasound: 36
- Embryo Transfers: 200 (84.4%)

Total Pregnancies: 56

Non-viable pregnancies: 14 (25%)

- Spontaneous Abortions: 12
- Ectopic Pregnancies: 2

Viable pregnancies: 42 (75%)

Births: 46

- Live Births: 44
- Stillborns: 2

Multiple pregnancies: 8 (19%)

- Twins: 7
- Triplets: 1

Pregnancy Rate per Follicular Aspiration Cycle: 23.2%

Pregnancy rate per Embryo Transfer Cycle: 27.5%

Take home baby rate per Follicular Aspiration Cycle: 17.3%

Take home baby rate per Embryo Transfer Cycle: 20.5%

On the basis of our previous experience, we counsel our patients on their prognosis for pregnancy and outcome in the following manner:

1) The couple has a 1 in 4 chance of becoming pregnant.

2) One out of 4 pregnancies miscarries.

3) One out of 5 viable pregnancies is a multiple pregnancy.

4) The couple has about a 1 out of 5 chance of taking home 1 or more babies.

5) The incidence of babies born with birth defects is population incidence or 2 to 3% for serious congenital anomalies.

In summary, we have a Community Hospital based IVF program that has been in existence for over 5 1/2 years and has been operating at a very steady pace with consistent results. We provide a very much appreciated service for those couples in our community who have a long-standing problem of infertility, which cannot be resolved with the more conventional forms of therapy.

Robert D. Visscher, M. D.
Director
Robert D Visscher MD.

IVF/GIFT SURVEY

Hutzel Hospital/Wayne State University
CLINIC NAME: In Vitro Fertilization Program
ADDRESS: 4707 St. Antoine
Detroit, MI 48201

CONTACT PERSON: Charla M. Blacker, M.D. and Kenneth A. Ginsburg, M.D.
PHONE NUMBER: (313) 745-7693

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    (a) Private ______
    (b) Community hospital based ______
    (c) University based X
    (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 5

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 5

6. How many other professionals participate in your clinic?
    (a) Physicians 0
    (b) Laboratory Scientists (PhDs) 2
    (c) Nurses 2
    (d) Embryo Lab Technicians/Technologists 2
    (e) Other Lab Technicians/Technologists 2
    (f) Radiology (Ultrasound) Technicians 2
    (g) Psychologists/Counselors 0
    (h) Secretaries 3
    (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 26

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 6/1983 GIFT 10/1985

9. How many different patients were stimulated?
1987 IVF 128 1988 IVF 92
GIFT 1 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 162 1988 IVF 112
GIFT 1 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 124 1988 92

How many embryo transfer cycles were performed?
1987 98 1988 67

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 78 61% 1988 IVF 57 62%
GIFT 1 100% GIFT 1 100%
(b) Endometriosis:
1987 IVF 20 16% 1988 IVF 22 24%
GIFT 0 0% GIFT 0 0%
(c) Male infertility:
1987 IVF 10 8% 1988 IVF 7 8%
GIFT 0 0% GIFT 0 0%
(d) Unexplained infertility:
1987 IVF 6 5% 1988 IVF 3 3%
GIFT 0 0% GIFT 0 0%
(e) Other (explain): N/A
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 27 21% 1988 IVF 30 33%
GIFT 0 0% GIFT 0 0%
(b) 31-35:
1987 IVF 53 41% 1988 IVF 34 37%
GIFT 1 100% GIFT 1 100%
(c) 36-40:
1987 IVF 30 23% 1988 IVF 24 26%
GIFT 0 0% GIFT 0 0%

(d) 41-45:
1987 IVF 16 13 % 1988 IVF 3 3 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 2 2 % 1988 IVF 1 1 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 18 1988 IVF 6
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 11 1988 IVF 2
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 4
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 2 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 18 % ____________
GIFT 0 0 % ____________

1988 IVF 1 17 % Twins
GIFT 0 0 % ____________

21. What are the qualifications of the director of the embryo laboratory? see attached sheet

22. Who supervises the laboratory director? see attached sheet

23. Does the clinic participate in an external laboratory proficiency testing program? see attached sheet
If the answer is yes, please specify which program.
see attached sheet

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** Yes

27. **Does the clinic train individuals in IVF or GIFT?** Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    - **(a) Physicians** 8
    - **(b) Laboratory scientists (PhDs)** 0
    - **(c) Embryo laboratory technicians/technologists** 4
    - **(d) Nurses** ______
    - **(e) Other (explain)** ______

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

The Hutzel Hospital/Wayne State University In Vitro Fertilization Program accepts patients from the private practice of the individual physicians within the division and also, referrals from outside physicians, and consists of a diversified infertility population. Frequently, there is more than one etiologic factor in the infertility. It is usually reserved as treatment of last resort after all other modalities have failed to achieve pregnancy, and was not done routinely during diagnostic laparoscopies. This probably skews the results to a decreased percentage of patients, as patients who would have conceived by other means have been eliminated from our population.

Ovulation induction regimens include: Pergonal, Metrodin, or a combination of Pergonal and Metrodin along with HCG. Luteal phase support using IM progesterone is given starting on day of retrieval; Clomiphene citrate is used only rarely in our clinical setting. Occassional patients with histories of premature luteinization or ovulation have been placed on GnRH agonists in combination with Metrodin or Pergonal.

IVF/GIFT SURVEY

21. Anthony Sacco, Ph.D.; 22 years research experience working with sperm and eggs; 14 years experience as Director of Andrology Lab; 6 years as Director of Human IVF Laboratory.

22. Responsible to the Director of the IVF Program, Kamran Moghissi, MD.

23. Yes - The College of American Pathologists; World Health Organization External Quality Control Survey.

IVF/GIFT SURVEY

CLINIC NAME: William Beaumont Hospital IVF Program
ADDRESS: 3601 West 13 Mile Road
Royal Oak, Michigan - 48072

Director: S. J. Behrman, M.D.
CONTACT PERSON: Stan A. Beyler, Ph.D.
PHONE NUMBER: (313) 288-7937

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Nov. 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 4

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 5

6. How many other professionals participate in your clinic?
   - (a) Physicians 5
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 4
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 3
   - (f) Radiology (Ultrasound) Technicians Departmental (6)
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) Nuclear Medicine & Immuno-Andrology Lab
     IVF Research

7. How many years has your infertility clinic been in operation? 11 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF July, 1983 GIFT November, 1986

9. How many different patients were stimulated?
1987 IVF 95 1988 IVF 124
GIFT 2 GIFT 6

10. How many stimulation cycles were performed?
1987 IVF 115 1988 IVF 153
GIFT 2 GIFT 6

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 100 1988 119

How many embryo transfer cycles were performed?
1987 80 1988 106

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 2 1988 6

13. What were the number and percentage of patients on IRB approved research protocols?
1987 5 4 % 1988 3 2 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 56 49 % 1988 IVF 68 44 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 23 20 % 1988 IVF 24 16 %
GIFT 0 0 % GIFT 1 17 %
(c) Male infertility:
1987 IVF 14 12 % 1988 IVF 26 17 %
GIFT 0 0 % GIFT 1 17 %
(d) Unexplained infertility:
1987 IVF 6 5 % 1988 IVF 20 13 %
GIFT 1 50 % GIFT 2 33 %
(e) Other (explain): Peritoneal/DES/Uterine factors
1987 IVF 14 12 % 1988 IVF 14 10 %
GIFT 1 50 % GIFT 2 33 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 25 22 % 1988 IVF 19 12 %
GIFT 0 0 % GIFT 0 0 %
(b) 31-35:
1987 IVF 54 47 % 1988 IVF 57 37 %
GIFT 1 50 % GIFT 2 33 %
(c) 36-40:
1987 IVF 30 26 % 1988 IVF 58 38 %
GIFT 1 50 % GIFT 3 50 %

(d) 41-45:
1987 IVF 4 3 % 1988 IVF 19 12 %
GIFT 0 0 % GIFT 1 17 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 16 1988 IVF 14
GIFT 1 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 10 1988 IVF 2
GIFT 1 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 7
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 4 40 % 3 twins, 1 quintuplet
GIFT 0 0 % no multiples

1988 IVF 2 100 % 2 twins
GIFT 0 0 % no multiples

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Physiology (Reproductive); Research experience in IVF at the graduate level and as a post-doctoral fellow, prior to clinical IVF work.

22. Who supervises the laboratory director? The program director

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? yes

27. Does the clinic train individuals in IVF or GIFT? yes* **If the answer is yes, how many individuals in the** (see below) **following specialties have been trained?**

(a) Physicians 6
(b) Laboratory scientists (PhDs) 2
(c) Embryo laboratory technicians/technologists 8
(d) Nurses 7
(e) Other (explain)

*Although we do not run an organized training program per se, we have trained a number of individuals by special arrangement only.

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The majority of our patients tend to be those whose infertility has been of long duration (2-10 years) or have problems that can only be helped through IVF; in other words, older patients and those in which IVF is a last resort. This is in contrast to some programs which either select only the "best" candidates and turn away the rest, or put patients through IVF or GIFT prior to exhausting more conventional treatments. Also the date provided represents all of our patients (experimental stimulation protocols have been included). Our "standard" stimulation protocol gives us a pregnancy rate per embryo transfer of 25% (35/140), with 63% of these going to delivery.

IVF/GIFT SURVEY

CLINIC NAME: SCHI Reproductive Endocrinology
ADDRESS: Saginaw Cooperative Hospitals, Inc.
1000 Houghton
Saginaw, MI 48602

CONTACT PERSON: M.H. Fakih, M.D.
PHONE NUMBER: (517) 771-6838

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11-30-88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ________
   - (b) Community hospital based ________
   - (c) University based x
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 7

6. How many other professionals participate in your clinic?
   - (a) Physicians 2
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 3
   - (e) Other Lab Technicians/Technologists ________
   - (f) Radiology (Ultrasound) Technicians ________
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 2½

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF April, 1987 GIFT April, 1987

9. How many different patients were stimulated?
1987 IVF 28 1988 IVF 49
GIFT 34 GIFT 77

10. How many stimulation cycles were performed?
1987 IVF 49 1988 IVF 79
GIFT 45 GIFT 131

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 41 1988 74

How many embryo transfer cycles were performed?
1987 41 1988 73

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 42 1988 109

13. What were the number and percentage of patients on IRB approved research protocols?
1987 2 7 % 1988 7 10 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 15 54 % 1988 IVF 26 53 %
GIFT 4 12 % GIFT 10 13 %
(b) Endometriosis:
1987 IVF 6 21 % 1988 IVF 6 12 %
GIFT 11 32 % GIFT 27 35 %
(c) Male infertility:
1987 IVF 2 7 % 1988 IVF 15 31 %
GIFT 9 26 % GIFT 13 17 %
(d) Unexplained infertility:
1987 IVF 3 11 % 1988 IVF 1 2 %
GIFT 10 29 % GIFT 21 27 %
(e) Other (explain): Premature Ovarian Failure
1987 IVF 2 7 % 1988 IVF 1 2 %
GIFT 0 0 % GIFT 6 8 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 9 32 % 1988 IVF 16 33 %
GIFT 19 56 % GIFT 33 43 %
(b) 31-35:
1987 IVF 17 61 % 1988 IVF 22 45 %
GIFT 10 29 % GIFT 32 42 %
(c) 36-40:
1987 IVF 1 4 % 1988 IVF 7 14 %
GIFT 4 12 % GIFT 8 10 %

(d) 41-45:
1987 IVF 1 4 % 1988 IVF 4 8 %
GIFT 1 3 % GIFT 4 5 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 6 1988 IVF 14
GIFT 14 GIFT 50

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 4 1988 IVF 2
GIFT 10 GIFT 12

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 10
GIFT 0 GIFT 33

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 0
GIFT 1 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 25 % One set of twins
GIFT 6 60 % Five sets of twins, one set triplets

1988 IVF 1 50 % One set of triplets
GIFT 4 36 % Three sets of twins, one set triplets

21. What are the qualifications of the director of the embryo laboratory? Ph.D. Reproductive Biology

22. Who supervises the laboratory director? Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ________
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Our clinic was the first to report on the use of follicular fluid to enhance sperm function in patients undergoing assisted reproductive technology. Since we started this new technique, we noted a doubling in our pregnancy rates and we have had many reproductive surgeons visit our program to try to establish similar techniques in their programs. We also offer the Zygote Intrafallopiam Transfer (ZIFT) procedure which is used in cases of severe low sperm count and we have had five pregnancies with this procedure.

IVF/GIFT SURVEY

CLINIC NAME: University of Michigan Medical Center
ADDRESS: Division of Reproductive Endocrinology & Infertility
Department of Obstetrics & Gynecology
L2021 Women's Hospital/D2202 MPB Box 0718
Ann Arbor MI 48109-0718
CONTACT PERSON: John F. Randolph, Jr., M.D.
PHONE NUMBER: (313) 936-7401

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private
   (b) Community hospital based
   (c) University based X
   (d) Other (explain)

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   (a) Physicians
   (b) Laboratory Scientists (PhDs) 2
   (c) Nurses 3
   (d) Embryo Lab Technicians/Technologists 3
   (e) Other Lab Technicians/Technologists 3
   (f) Radiology (Ultrasound) Technicians 0
   (g) Psychologists/Counselors 0
   (h) Secretaries 1
   (i) Other (specify)

7. How many years has your infertility clinic been in operation? 4½

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 1984 GIFT 1986

9. How many different patients were stimulated?
1987 IVF 49 1988 IVF 55
GIFT 2 GIFT 4
Combined 8 Combined 14

10. How many stimulation cycles were performed?
1987 IVF 75 1988 IVF 83
GIFT 2 GIFT 4

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 60 1988 61

How many embryo transfer cycles were performed?
1987 58 1988 57

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 10 1988 18
(8 combined with IVF) (14 combined with IVF)

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number*and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 22 45 % 1988 IVF 26 47 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 13 27 % 1988 IVF 8 15 %
GIFT 6 60 % GIFT 6 33 %
(c) Male infertility:
1987 IVF 4 8 % 1988 IVF 8 15%
GIFT 1 10% GIFT 4 22%
(d) Unexplained infertility:
1987 IVF 10 20% 1988 IVF 12 22 %
GIFT 3 30% GIFT 8 45%
(e) Other (explain): Donor oocytes
1987 IVF 0 0 % 1988 IVF 1 2 %
GIFT 0 0 % GIFT 0 0 %

*Numbers for each group include combined procedures.

15. What were the number* and percentage of patients in the following age groups:
(a) <31:
1987 IVF 10 20% 1988 IVF 21 38%
GIFT 3 30% GIFT 8 44 %
(b) 31-35:
1987 IVF 31 63 % 1988 IVF 22 40%
GIFT 7 70 % GIFT 10 56 %
(c) 36-40:
1987 IVF 8 16 % 1988 IVF 12 22%
GIFT 0 0 % GIFT 0 0 %

*Numbers for each group include combined procedures.

(d) 41-45:
1987 IVF 1 2 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 8 1988 IVF 8
GIFT 0 GIFT 0
Combined 1 Combined 6

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 3 1988 IVF 2
GIFT 0 GIFT 0
Combined 2 Combined 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 3
GIFT 0 GIFT 0
Combined 3

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 % ____
GIFT 0 0 % ____

1988 IVF 1 50% Twins
GIFT ___ ___ % ____

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Reproductive Endocrinology; extensive experience in animal gamete and embryo systems

22. Who supervises the laboratory director? John F. Randolph, Jr., M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    - (a) Physicians ________
    - (b) Laboratory scientists (PhDs) ________
    - (c) Embryo laboratory technicians/technologists ______
    - (d) Nurses ________
    - (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The Clinic participates in the most successful Electro-ejaculation Program available for anejaculatory infertility. The patient population is thus skewed to male factor infertility.

IVF/GIFT SURVEY

RECEIVED
DEC 7 1988
Ron Wyden

CLINIC NAME: CENTER FOR REPRODUCTIVE MEDICINE - OAKWOOD HOSPITAL
ADDRESS: OAKWOOD MEDICAL BUILDING
18181 OAKWOOD BLVD.
SUITE 100G
DEARBORN, MI 48124
CONTACT PERSON: DAVID M. MAGYAR, D.O.
PHONE NUMBER: (313) 593-5880

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/3/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    (a) Private ______
    (b) Community hospital based X
    (c) University based ______
    (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? TWO

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? TWO

6. How many other professionals participate in your clinic?
    (a) Physicians TWO
    (b) Laboratory Scientists (PhDs) TWO
    (c) Nurses FOUR
    (d) Embryo Lab Technicians/Technologists TWO
    (e) Other Lab Technicians/Technologists ONE
    (f) Radiology (Ultrasound) Technicians FIVE
    (g) Psychologists/Counselors ONE
    (h) Secretaries TWO
    (i) Other (specify) TWO MEDICAL ASSISTANTS
    THREE RECEPTIONISTS

7. How many years has your infertility clinic been in operation? FIVE MONTHS

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 11/22/88 GIFT N/A

9. How many different patients were stimulated?
1987 IVF N/A 1988 IVF ONE
GIFT N/A GIFT -0-

10. How many stimulation cycles were performed?
1987 IVF N/A 1988 IVF ONE
GIFT N/A GIFT -0-

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 N/A 1988 ONE

How many embryo transfer cycles were performed?
1987 N/A 1988 ONE

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 N/A 1988 N/A

13. What were the number and percentage of patients on IRB approved research protocols?
1987 N/A % 1988 N/A %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF N/A % 1988 IVF 1 100%
GIFT N/A % GIFT N/A %
(b) Endometriosis:
1987 IVF N/A % 1988 IVF N/A %
GIFT N/A % GIFT N/A %
(c) Male infertility:
1987 IVF N/A % 1988 IVF N/A %
GIFT N/A % GIFT N/A %
(d) Unexplained infertility:
1987 IVF N/A % 1988 IVF N/A %
GIFT N/A % GIFT N/A %
(e) Other (explain):
1987 IVF N/A % 1988 IVF N/A %
GIFT N/A % GIFT N/A %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF N/A % 1988 IVF -0- -0- %
GIFT N/A % GIFT N/A %
(b) 31-35:
1987 IVF N/A % 1988 IVF 1 100%
GIFT N/A % GIFT N/A %
(c) 36-40:
1987 IVF N/A % 1988 IVF -0- -0- %
GIFT N/A % GIFT N/A %

(d) 41-45:
1987 IVF N/A % 1988 IVF -0- -0- %
GIFT N/A % GIFT N/A %

(e) >45:
1987 IVF N/A % 1988 IVF -0- -0- %
GIFT N/A % GIFT N/A %

16. How many clinical pregnancies were produced?
1987 IVF ____ 1988 IVF ____ UNKNOWN AT PRESENT
GIFT ____ GIFT ____

17. How many women delivered live infants from IVF/GIFT?
1987 IVF N/A 1988 IVF N/A
GIFT N/A GIFT N/A

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF N/A 1988 IVF N/A
GIFT N/A GIFT N/A

19. How many ectopic pregnancies resulted?
1987 IVF N/A 1988 IVF N/A
GIFT N/A GIFT N/A

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% N/A
GIFT ___ ___% N/A

1988 IVF ___ ___% N/A
GIFT ___ ___% N/A

21. What are the qualifications of the director of the embryo laboratory? BOARD CERTIFIED M.D. PATHOLOGIST

22. Who supervises the laboratory director? PhD REPRODUCTIVE BIOLOGIST

23. Does the clinic participate in an external laboratory proficiency testing program? NO. I AM NOT AWARE OF AN EXTERNAL
If the answer is yes, please specify which program.
PROGRAM FOR IVF LABS - WOULD APPRECIATE INFORMATION.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? DR. MAGYAR AND DR. HAYES ARE MEMBERS. THE CENTER HAS NOT PERFORMED ENOUGH IVF CYCLES YET TO APPLY FOR MEMBERSHIP.

27. Does the clinic train individuals in IVF or GIFT? NOT AT PRESENT. **If the answer is yes, how many individuals in the following specialties have been trained?**

  (a) Physicians ________
  (b) Laboratory scientists (PhDs) _______
  (c) Embryo laboratory technicians/technologists _____
  (d) Nurses _______
  (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Our Directors, David M. Magyar, D.O. and Maria F. Hayes, M.D. developed Michigan's first IVF Clinic in 1983 at Hutzel Hospital/Wayne State University in Detroit, Michigan. D rs. Magyar and Hayes supervised ovulation induction, performed most ovum retrievals and trained six fellows in reproductive endocrinology/IVF betwen June of 1983 and June of 1988.

The Center for Reproductive Endocrinology is a full service facility in conjunction with and on site at, Oakwood Hospital, a 615 bed community teaching hospital with an approved residency program in Obstetrics and Gynecology.

Drs. Magyar and Hayes have teaching appointments at Wayne State University School of Medicine.

We expect to perform approximately forty stimulation cycles over the next eight to ten weeks. We appreciate this opportunity to participate in your investigation and look forward to forwarding to you more meaningful data in the future.

IVF/GIFT SURVEY

CLINIC NAME: Women's Health Center
ADDRESS: University of Minnesota
Department of Obstetrics and Gynecology
Box 395, 420 Delaware Street SE
Minneapolis, MN 55455
CONTACT PERSON: George E. Tagatz, M.D.
PHONE NUMBER: 612-626-3232

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/12/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based ______
   (c) University based X
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1 (fellow)

6. How many other professionals participate in your clinic?
   (a) Physicians 4
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 1 Nurse Practitioner
   (d) Embryo Lab Technicians/Technologists 2.5
   (e) Other Lab Technicians/Technologists 0
   (f) Radiology (Ultrasound) Technicians 1
   (g) Psychologists/Counselors 1
   (h) Secretaries 2
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 16

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 83 GIFT 85

9. How many different patients were stimulated?
1987 IVF 63 1988 IVF 125
GIFT 0 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 72 1988 IVF 139
GIFT 0 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 52 1988 103

How many embryo transfer cycles were performed?
1987 43 1988 93

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0% 1988 0 0%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ ___%
approx. 90% GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
approx. 5% GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
approx. 15% GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
approx. 5% GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ______________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF ___ ___%
0-2% GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF ___ ___%
50-60% GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF ___ ___%
30-40% GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
<1% GIFT ___ ___% GIFT ___ ___%
(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
0% GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 16 1988 IVF 18
GIFT 0 GIFT 1 (twins)

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 9 (3 set twins) 1988 IVF 2
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 10
GIFT 0 GIFT 1 (twins)

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 3 30 % 3 set twins
GIFT 0 0 % ___

1988 IVF 2 20 % 1 set twins delivered; 1 twin preg. ongoing
GIFT 1 100 % 1 set twins ongoing

21. What are the qualifications of the director of the embryo laboratory? Ph.D. Human Reproductive Physiology, Post doctoral training - MRC Mammalian Development Unit, London, approximately 20 hours Cognate hrs/year (CME)

22. Who supervises the laboratory director? Dr. George E. Tagatz

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. *Is the clinic a member of the* Society for Assisted Reproductive Technology? yes

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 1/year
    (b) Laboratory scientists (PhDs) no
    (c) Embryo laboratory technicians/technologists 1/year
    (d) Nurses 1/year
    (e) Other (explain) --

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: University of Mississippi Medical Center
ADDRESS: Department of Ob-Gyn
2500 N. State St.
Jackson, MS 39216

CONTACT PERSON: Dr. Bryan D. Cowan
PHONE NUMBER: 601-984-5330

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians ______
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 3
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 4
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 3
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 4

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1984 GIFT 1985

9. How many different patients were stimulated?
1987 IVF 48 1988 IVF 43
GIFT 2 GIFT 4

10. How many stimulation cycles were performed?
1987 IVF 85 1988 IVF 65
GIFT 2 GIFT 4

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 53 1988 48

How many embryo transfer cycles were performed?
1987 46 1988 36

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 2

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 28 58.3% 1988 IVF 26 60.5%
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 9 18.8% 1988 IVF 10 23.2%
GIFT 0 0 % GIFT 2 50 %
(c) Male infertility:
1987 IVF 2 4.2% 1988 IVF 2 4.7%
GIFT 1 50 % GIFT 1 25 %
(d) Unexplained infertility:
1987 IVF 4 8.3% 1988 IVF 1 2.3%
GIFT 0 0 % GIFT 0 0 %
(e) Other (explain): Anovulation, Luteal defect, PCOD
1987 IVF 5 10.4% 1988 IVF 4 9.3%
GIFT 1 50% GIFT 1 25 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 19 39.[illegible]% 1988 IVF 12 27.9%
GIFT 1 50% GIFT 2 50 %
(b) 31-35:
1987 IVF 17 35.4% 1988 IVF 16 37.2%
GIFT 1 50% GIFT 2 50%
(c) 36-40:
1987 IVF 10 20.8% 1988 IVF 13 30.2%
GIFT 0 0 % GIFT 0 0 %

(d) 41-45:
1987 IVF 2 4.2 % 1988 IVF 2 4.7 %
GIFT 0 0 % GIFT 0 0 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 13 1988 IVF 11
GIFT 1 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 12 1988 IVF 2
GIFT 1 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 6
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 2
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 8.3 % 1 set of twins
GIFT 0 0 %

1988 IVF 1 50 % 1 set of twins
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? PhD. in Reproductive Physiology

22. Who supervises the laboratory director? Division Director; Departmental Chairman

23. Does the clinic participate in an external laboratory proficiency testing program? yes
If the answer is yes, please specify which program.
College of American Pathologists (CAP) Survey

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? yes

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 0
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 2
    (d) Nurses 3
    (e) Other (explain) 0

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Jewish Hospital at Washington University Medical Center
ADDRESS: Department of Obstetrics and Gynecology
216 S. Kingshighway
St Louis, Mo. 63110

CONTACT PERSON: Ronald C Strickler M.D. / Nena Swank, R.N.
PHONE NUMBER: (314) 454-7834

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based ✓
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? WF Program 5. Washington Univ Consultants 7

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? Washington Univ Consultants, 19

6. How many other professionals participate in your clinic?
   - (a) Physicians 2
   - (b) Laboratory Scientists (PhDs) ______
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 2 (MSc, Ph.D)
   - (e) Other Lab Technicians/Tecnnologists 2
   - (f) Radiology (Ultrasound) Technicians 1-2
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ______

These are the active staff. We have available consultants in every aspect of medical science

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1987

9. How many different patients were stimulated?
1987 IVF 51 1988 IVF 62
GIFT 2 GIFT 2

10. How many stimulation cycles were performed?
1987 IVF 77 1988 IVF 99
GIFT 2 GIFT 2

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 53 1988 55

How many embryo transfer cycles were performed?
1987 42 1988 42

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 2 1988 2

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0 % 1988 ___ 0 % in 1987, we no longer asked the IRB to approve the clinical program

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 24 57 % 1988 IVF 33 53 %
GIFT 0 ___ % GIFT 0 ___ %
(b) Endometriosis:
1987 IVF 8 16 % 1988 IVF 15 24 %
GIFT 0 ___ % GIFT 0 ___ %
(c) Male infertility:
1987 IVF 3 6 % 1988 IVF 2 3 %
GIFT 1 50 % GIFT 1 50 %
(d) Unexplained infertility:
1987 IVF 4 8 % 1988 IVF 0 ___ %
GIFT 1 50 % GIFT 1 50 %
(e) Other (explain): ______________
1987 IVF 7 14 % 1988 IVF 12 19 %
GIFT ___ ___ % GIFT ___ ___ %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 12 24 % 1988 IVF 9 16 %
GIFT 2 100 % GIFT 1 50 %
(b) 31-35:
1987 IVF 23 45 % 1988 IVF 27 44 %
GIFT 0 ___ % GIFT 1 50 %
(c) 36-40:
1987 IVF 13 26 % 1988 IVF 20 32 %
GIFT 0 ___ % GIFT 0 ___ %

(d) 41-45:
1987 IVF 3 6 % 1988 IVF 6 10 %
GIFT 0 ___ % GIFT 0 ___ %

(e) >45:
1987 IVF 0 ___ % 1988 IVF 0 ___ %
GIFT 0 ___ % GIFT 0 ___ %

16. How many clinical pregnancies were produced?
1987 IVF 6 1988 IVF 9
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 5 1988 IVF 4
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 2
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 20 % Twins
GIFT 0 ___ % ___

1988 IVF 2 33 % Triplets x 2
GIFT 0 ___ % ___

21. What are the qualifications of the director of the embryo laboratory? M.Sc. 10 years experience in human tissue culture cytogenetics, and cytology

22. Who supervises the laboratory director? Program director

23. Does the clinic participate in an external laboratory proficiency testing program? No.
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? yes

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 4
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 3
    (d) Nurses 2
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The in vitro fertilization program is one reproductive technology option available within our unit which provides a full range of Obstetrical and Gynecologic consultative services to the St. Louis and adjacent Missouri/Illinois communities.

IVF/GIFT SURVEY

CLINIC NAME: Univ. of NE Med Ctr
ADDRESS: Dept OB-Gyn
Omaha, NE 68144

CONTACT PERSON: Ponjola Coney M.D.
PHONE NUMBER: 402-559-6151

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/87 - 12/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based ______
   [✓ (c)] University based ✓
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? one

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? one Same as #4

6. How many other professionals participate in your clinic?
   (a) Physicians ______
   [✓ (b)] Laboratory Scientists (PhDs) 1
   [✓ (c)] Nurses 1
   [✓ (d)] Embryo Lab Technicians/Technologists 1
   (e) Other Lab Technicians/Technologists ______
   (f) Radiology (Ultrasound) Technicians ______
   [✓ (g)] Psychologists/Counselors 1
   [✓ (h)] Secretaries 1
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? ONE for IVF Infertility Specialist x 5 yrs
Had IVF program at previous hospital

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF JAN. 1988 GIFT July, 1988

Univ. of OK

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF 25
GIFT ______ GIFT 4

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF 60
GIFT ______ GIFT 4

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ________ 1988 40

How many embryo transfer cycles were performed?
1987 ________ 1988 25

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ________ 1988 4

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ 0%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF 24/95%
GIFT ___ ___% GIFT ___ 0%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 1/3% %
GIFT ___ ___% GIFT 2/50%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 3/10%
GIFT ___ ___% GIFT ___ 0%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ 0%
GIFT ___ ___% GIFT 1 25%
(e) Other (explain): ______________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF 5 20%
GIFT ___ ___% GIFT ___ 0%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF 10 40%
GIFT ___ ___% GIFT 4 100%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF 10 40%
GIFT ___ ___% GIFT ___ 0%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ 0%
GIFT ___ ___% GIFT ___ 0%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ 0%
GIFT ___ ___% GIFT ___ 0%

16. How many clinical pregnancies were produced?
1987 IVF ____ 1988 IVF 2
GIFT ____ GIFT 2

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ____ 1988 IVF 1
GIFT ____ GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ____ 1988 IVF 1
GIFT ____ GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF ____ 1988 IVF 0
GIFT ____ GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ____________________
GIFT ___ ___% ____________________

1988 IVF ___ ___% ____________________
GIFT 2 50% Twins

21. What are the qualifications of the director of the embryo laboratory? PhD reproductive physiology

22. Who supervises the laboratory director? Director is supervisor

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** NO

27. **Does the clinic train individuals in IVF or GIFT?** NO
If the answer is yes, how many individuals in the following specialties have been trained?
(a) **Physicians** ________
(b) **Laboratory scientists (PhDs)** ________
(c) **Embryo laboratory technicians/technologists** ______
(d) **Nurses** ________
(e) **Other (explain)** ________

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

This program is one year old. The laboratory required a great deal of equipment updating and relocation during this first year. There were mechanical problems that first became apparent during treatment cycles. all of these problems were corrected and the time of actual operation was approximately 4 months during the year. The patients were informed of these problems and are being compensated with a free cycle in the future. We are confident of our ability to provide a quality and honest service in this area in subsequent years. —

J Carey M.D.

IVF/GIFT SURVEY

CLINIC NAME: Methodist Hospital
ADDRESS: 8303 Dodge Street
Omaha Ne

CONTACT PERSON: Julie Chamberlain
PHONE NUMBER: 402 390 4138

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Dec. 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? none

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? three

6. How many other professionals participate in your clinic?
   - (a) Physicians ________
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 3
   - (e) Other Lab Technicians/Technologists ________
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors ________
   - (h) Secretaries ________
   - (i) Other (specify) Social Worker (MSW) 1

7. How many years has your infertility clinic been in operation? 1½

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF April 1987 GIFT August 1987

9. How many different patients were stimulated?
1987 IVF 17 1988 IVF 12 (1 IVF & GIFT) included
GIFT 2 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 10 1988 IVF 19 (IVF & GIFT) included
GIFT 4 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 11 1988 17

How many embryo transfer cycles were performed?
1987 9 1988 17 (includes 1 IVF & GIFT)

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 2 1988 1

N/A (13.) What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 6 ___% 1988 IVF 8 ___%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 1 ___% 1988 IVF ___ ___%
GIFT 1 ___% GIFT 2 ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 2 ___%
GIFT ___ ___% GIFT 2 ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 1 ___% GIFT ___ ___%
(e) Other (explain): ____________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 3 ___% 1988 IVF 2 ___%
GIFT 1 ___% GIFT 2 ___%
(b) 31-35:
1987 IVF 4 ___% 1988 IVF 4 ___%
GIFT ___ ___% GIFT 1 ___%
(c) 36-40:
1987 IVF 1 ___% 1988 IVF 2 ___%
GIFT 2 ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

0 ~~(e)~~ >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF ___ 1988 IVF 3
GIFT ___ GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF ___
GIFT ___ GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 2
GIFT ___ GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF 0
GIFT ___ GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ______________
GIFT ___ ___% ______________

1988 IVF ___ ___% ______________
GIFT ___ ___% ______________

21. What are the qualifications of the director of the embryo laboratory? PHD

22. Who supervises the laboratory director? Medical Director

23. Does the clinic participate in an external laboratory proficiency testing program? ______________
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? ________________

27. Does the clinic train individuals in IVF or GIFT? ______ If the answer is yes, how many individuals in the following specialties have been trained?
    - (a) Physicians ______
    - (b) Laboratory scientists (PhDs) _______
    - (c) Embryo laboratory technicians/technologists _____
    - (d) Nurses ______
    - (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Northern Nevada Fertility Center
ADDRESS: 350 W. 6th Street, St #3AB
Reno, Nevada 89503

CONTACT PERSON: Dr. Victor Knutzen
PHONE NUMBER: 702-688-5600

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 1-30-89

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ____
   - (c) University based ____
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 3
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 0
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 3.3
   - (i) Other (specify) Student/Technology

7. How many years has your infertility clinic been in operation? 5 1/2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1986

9. **How many different patients were stimulated?**
1987 IVF 142 1988 IVF 111
GIFT 5 GIFT 3

10. **How many stimulation cycles were performed?**
1987 IVF 188 1988 IVF 155
GIFT 5 GIFT 3

11. **For those clinics offering IVF:**
How many egg recovery procedures were performed?
1987 139 1988 123

How many embryo transfer cycles were performed?
1987 128 1988 115

12. **How many GIFT procedures (attempted egg recoveries) were performed?**
1987 5 1988 3

13. **What were the number and percentage of patients on IRB approved research protocols?**
1987 ___ 0 % 1988 ___ 0 %

14. **What were the number and percentage of patients treated for:**
(a) Tubal factor:
1987 IVF 138 73 % 1988 IVF 116 73 %
GIFT ___ 0 % GIFT ___ 0 %

We note multiple
diagnosis &
indications .
Therefore these
numbers do not
equal 100%.

(b) Endometriosis:
1987 IVF 79 42 % 1988 IVF 62 40 %
GIFT 1 ___ % GIFT 1 ___ %
(c) Male infertility:
1987 IVF 60 31 % 1988 IVF 62 40 %
GIFT 2 ___ % GIFT 1 ___ %
(d) Unexplained infertility:
1987 IVF 12 6 % 1988 IVF 8 5 %
GIFT 3 ___ % GIFT 1 ___ %
(e) Other (explain): Antibodies
1987 IVF 12 6 % 1988 IVF 32 ___ %
GIFT ___ ___ % GIFT ___ ___ %

15. **What were the number and percentage of patients in the following age groups:**
(a) <31:
1987 IVF 22 154 % 1988 IVF 17 162 %
GIFT ___ ___ % GIFT ___ ___ %

Of the patients
in #9

(b) 31-35:
1987 IVF 43 30 % 1988 IVF 43 38.2 %
GIFT 1 .007 % GIFT 2 .02 %
(c) 36-40:
1987 IVF 47 33 % 1988 IVF 34 31.7 %
GIFT 3 .02 % GIFT 1 .009 %

Two were
IVF/GIFT combo.

(d) 41-45:
1987 IVF 27 19 % 1988 IVF 12 10.5%
GIFT 1 .007% GIFT 1 .008%

(e) >45:
1987 IVF ___ ___% 1988 IVF 1 .008%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 26 1988 IVF 25
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 17 1988 IVF 8
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 14
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 3 1988 IVF 3
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 6 ___% 6 sets twins
GIFT 0 ___% ___

1988 IVF 2 ___% 2 sets twins (Of on-going
GIFT ___ ___% pregnancies, I quad, I twin)

21. What are the qualifications of the director of the embryo laboratory? PHD. professor of Anatomy at Univ.of Nevada School of Medicine. has published numerous articles in international journals oncell culture procedures, human gamete research & mouse & human IVF protocols.

22. Who supervises the laboratory director?
-V.K. Knutzen MD, IVF Program Dir

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
State licensure

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
(a) Physicians 3
(b) Laboratory scientists (PhDs) 4
(c) Embryo laboratory technicians/technologists 2
(d) Nurses ______
(e) Other (explain) 1 laboratory asst. Trained post grad Board cert. obgyn in Honolulu.

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Comments to follow.

[redacted]

350 West Sixth Street
Reno, Nevada 89503
702·322·4521

NORTHERN
NEVADA
FERTILITY
CENTER

Victor Knutzen, M.D.
Medical Director

Carlos E. Soto-Albors, M.D.
Reproductive
Endocrinologist

Craig W. Klose, M.D.
Associate Medical
Director

Clifford J. Stratton, Ph.D.
Lab Director

Dianne Fuller, R.N., F.N.P.
Nurse Coordinator

Other Comments

NORTHERN NEVADA FERTILITY CENTER

Our clinic opened in 1983. It is a fully private free standing IVF infertility clinic. Responsible for more than 100 live births from IVF.

The majority of our patients come from out of the state of Nevada. Our program is designed to work in close cooperation with the patients home town physician. Our patients come to the clinic on approximately cycle day 9 and stay until cycle day 15 or 16.

Reno, Nevada is a tourist based town very close to Lake Tahoe. Because of the tourist economy there are many places to stay for very reasonable rates, as well as much to do during the free time of the treatment cycle. Our area is surrounded with skiing, lakes, and many historical sites.

Our clinic is committed to personal quality care. Our relatively small size allows us to get to know each of our patients and personalize the care to their needs. We are committed to the education and psychological care of each person who comes through our program. This includes follow-up contact with each couple.

Victor Knutzen

Victor Knutzen, M.D.
Medical Director

IVF/GIFT SURVEY

CLINIC NAME: Dartmouth-Hitchcock Medical Center
ADDRESS: Clinic 500
2 Maynard Street
Hanover, NH 03756

CONTACT PERSON: Paul Manganiello, M.D.
PHONE NUMBER: (603) 646-8255

RECEIVED
DEC 1 4 1988
Hon Ron Wyden

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians 3 radiologists; 2 anesthesiologists
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 5
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 0
   - (f) Radiology (Ultrasound) Technicians 4
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 10

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1986 GIFT None

9. How many different patients were stimulated?
1987 IVF 10 1988 IVF 9
GIFT ___ GIFT ___

10. How many stimulation cycles were performed?
1987 IVF 12 1988 IVF 10
GIFT ___ GIFT ___

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 9 1988 6

How many embryo transfer cycles were performed?
1987 6 1988 5

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 None ___% 1988 None ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 7 70% 1988 IVF 6 67%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 2 20% 1988 IVF 2 22%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): Immunological
1987 IVF 1 10% 1988 IVF 1 11%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 4 40% 1988 IVF 0 0%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF 3 30% 1988 IVF 5 56%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF 3 30% 1988 IVF 4 44%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 1 1988 IVF 2
GIFT ___ GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 1 1988 IVF 1
GIFT ___ GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 1
GIFT ___ GIFT ___

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT ___ GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0% No multiples
GIFT ___ ___%

1988 IVF 1 100% Twins
GIFT ___ ___%

21. What are the qualifications of the director of the embryo laboratory? PhD and 5 yr. postdoctoral work. Speciality Reproductive Physiology & Endocrinology. Experience in cell culture.

22. Who supervises the laboratory director?
Medical Director of IVF Program
Chairman of Maternal-Child Health
Chairman of Pathology

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
HHS 28-1012 28-1004 (in conjunction with Mary Hitchcock Memorial Hospital laboratories).

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Tentative

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
- **(a) Physicians** ________
- **(b) Laboratory scientists (PhDs)** _______
- **(c) Embryo laboratory technicians/technologists** _____
- **(d) Nurses** _______
- **(e) Other (explain)** ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The Dartmouth-Hitchcock Medical Center began offering IVF in 1986. Since that time our numbers of patients have been small but our success rate good. We have performed 22 egg harvests and achieved four clinical pregnancies (18%) resulting in two live births (one set of twins), one ongoing pregnancy and one spontaneous miscarriage. Dartmouth-Hitchcock Medical Center, associated with Dartmouth Medical School, is the only tertiary care facility in New Hampshire. As a part of this facility, our IVF program is an integral part of a complete reproductive counseling program providing services for this community.

The numbers of IVF patients at our clinic have been low for two important reasons. First, our clinic is situated in a rural setting two hours from either Burlington, Vermont, or Boston, Massachusetts. We draw patients from New Hampshire, Vermont, Maine, New York and Massachusetts, however, the largest population centers in New Hampshire tend to be in the southern part of the state where traditionally referral patterns have been to Boston. Since beginning to offer IVF, we have had about 30 couples/year express interest in our program and although we expect interest to continue at about this level, we do not foresee it increasing substantially in the near future. Second, we do not blindly push our patients into IVF. All patients expressing interest in the procedure must be medically appropriate for IVF. All perspective patients speak with a social worker and are encouraged to be realistic about the nationwide success rates for IVF, but also to consider other options open to them, including adoption. The goal of our program is to help couples have the family they desire by the means which best suit them.

IVF is a complicated technology and expertise in such technologies is maintained only by continued practice. Our successes speak for our ability to maintain expertise and to offer a quality program despite low patient numbers. Offering IVF at this facility allows us to provide well rounded quality care for infertile couples despite a rural setting.

IVF/GIFT SURVEY

CLINIC NAME: UMDNJ- New Jersey Medical School
ADDRESS: 150 Bergen Street
Newark, N.J. 07103
F342

CONTACT PERSON: Cecilia L. Schmidt, M.D.
PHONE NUMBER: (201) 456-6029 or 456-5438

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12-31-88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based ______
   (c) University based x
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 5

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 5

6. How many other professionals participate in your clinic?
   (a) Physicians 4
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 4
   (d) Embryo Lab Technicians/Technologists 2
   (e) Other Lab Technicians/Technologists 3
   (f) Radiology (Ultrasound) Technicians 0
   (g) Psychologists/Counselors Psychiatrist - 1
   (h) Secretaries 5
   (i) Other (specify) Administrator

7. How many years has your infertility clinic been in operation? 3

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 3/31/86 GIFT 4/6/87

9. How many different patients were stimulated?
1987 IVF 106 1988 IVF 128
GIFT 1 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 162 1988 IVF 166
GIFT 1 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 139 1988 156

How many embryo transfer cycles were performed?
1987 122 1988 141

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor: (Please attached sheet)
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ______________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 18 16 % 1988 IVF 21 14 %
GIFT 1 100% GIFT 0 0 %
(b) 31-35:
1987 IVF 47 42 % 1988 IVF 54 37 %
GIFT 0 0 % GIFT 1 100%
(c) 36-40:
1987 IVF 35 31 % 1988 IVF 48 33 %
GIFT 0 0 % GIFT 0 0 %

QUESTION (14)

		1987		1988	
		#	%	#	%
Tubal Factor	IVF	53	52%	85	64%
	GIFT	0	0	0	0
Endometriosis	IVF	21	21%	28	21%
	GIFT	0	0	0	0
Male Factor	IVF	49	48%	54	41%
	GIFT	0	100%	0	0
Unexplained	IVF	3	3%	5	4%
	GIFT	0	0	1	100%
DES Exposure	IVF	1	<1%	1	<1%
	GIFT	0	0	0	0
Oligoovulation	IVF	10	10%	6	4%
	GIFT	0	0	0	0
Premature Leutinization	IVF	1	<1%	1	<1%
	GIFT	0	0	0	0
Hypothalamic Amenorrhea	IVF	3	3%	2	1%
	GIFT	0	0	0	0
Polycystic Ovaries	IVF	7	7%	2	1%
	GIFT	0	0	0	0
Hyperprolactinemia	IVF	2	2%	4	3%
	GIFT	0	0	0	0
Cervical Factor	IVF	3	3%	2	1%
	GIFT	0	0	0	0
Luteal Phase Defect	IVF	11	11%	6	6%
	GIFT	0	0	0	0
Multiple Diagnosis	IVF	57	56%	58	44%
	GIFT	0	0	0	0

(d) 41-45:
1987 IVF 13 11 % 1988 IVF 23 16 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 20 1988 IVF 21
GIFT 0 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 12 +1 FET 1988 IVF 6 + 2 (FET)
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 9 + 5 (FET)
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 5 42 % Twins X 4, Triplets X 1
GIFT 0 0 %

1988 IVF 1 17 % Twins X 1
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? As per AFS guidelines

22. Who supervises the laboratory director? Cecilia L. Schmidt, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? Yes. The Laboratory is under the auspices of
If the answer is yes, please specify which program. [illegible]
Pathology and is accredited by C.A.P.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes - Board-approved fellowship for two first-year and two second-year fellows.

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 4 - Fellows in RE/Inf.
    (b) Laboratory scientists (PhDs) 1
    (c) Embryo laboratory technicians/technologists 3
    (d) Nurses 0
    (e) Other (explain) 0

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: UMDNJ - Robert Wood Johnson Medical School
ADDRESS: IVF Program: Dept. of OB/GYN
#1 Robert Wood Johnson Place, CN19
New Brunswick, NJ 08903

CONTACT PERSON: Joan Hammond
PHONE NUMBER: (201) 937-7711

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Jan '89
2. Does your clinic perform IVF/GIFT treatments? yes
   (If the answer is no, there is no need to complete the remainder of the questionnaire.)
3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______
4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3
5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 5
6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 0
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 2
   - (i) Other (specify) ______
7. How many years has your infertility clinic been in operation? 6 years
8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF Spring '83 GIFT Spring '85

9. How many different patients were stimulated?
1987 IVF [redacted] 60 1988 IVF ≈ 80
GIFT 0 GIFT 13

10. How many stimulation cycles were performed?
1987 IVF 138 1988 IVF [redacted] 182
GIFT 0 GIFT 13

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 76 1988 101

How many embryo transfer cycles were performed?
1987 61 1988 96

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 13

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ≈60 100% 1988 ≈90 100%

14. What were the number and percentage of patients treated for:

Approximates

(a) Tubal factor:
1987 IVF 36 66% 1988 IVF 48 60%
GIFT — — % GIFT 8 60 %
(b) Endometriosis:
1987 IVF 6 10% 1988 IVF 8 10 %
GIFT — — % GIFT 1 10 %
(c) Male infertility:
1987 IVF 6 10 % 1988 IVF 8 10 %
GIFT — — % GIFT 1 10 %
(d) Unexplained infertility:
1987 IVF 6 10 % 1988 IVF 8 10%
GIFT — — % GIFT 1 10 %
(e) Other (explain): ______
1987 IVF 6 10 % 1988 IVF 8 10 %
GIFT — — % GIFT 1 10 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 — % 1988 IVF 0 — %
GIFT 0 — % GIFT 4 33 %
(b) 31-35:
1987 IVF 12 20% 1988 IVF 16 20%
GIFT 0 ___ % GIFT 5 34 %
(c) 36-40:
1987 IVF 48 80 % 1988 IVF 64 80 %
GIFT 0 — % GIFT 4 33 %

(d) 41-45:
1987 IVF — % 1988 IVF — %
GIFT — % GIFT — %
(e) >45:
1987 IVF — % 1988 IVF — %
GIFT — % GIFT — %

16. How many clinical pregnancies were produced?
1987 IVF 21 1988 IVF 18
GIFT — GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 8 1988 IVF 11
GIFT — GIFT —

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF — 1988 IVF 2
GIFT — GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 3 5% twins
GIFT — %

1988 IVF 1 >1% twins
GIFT — %

21. What are the qualifications of the director of the embryo laboratory? Phd - Embryologist, Andrologist

22. Who supervises the laboratory director? Chairman dpt OB/GYN

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? yes

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 5
    (b) Laboratory scientists (PhDs) 6
    (c) Embryo laboratory technicians/technologists 10
    (d) Nurses 2
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Very active Cryo Preservation program

UMD
NEW JERSEY
University of Medicine & Dentistry of New Jersey
Robert Wood Johnson Medical School

Department of Obstetrics & Gynecology
Division of Reproductive Endocrinology-Infertility
201/937-7627

One Robert Wood Johnson Place - CN 19
New Brunswick, New Jersey, 08903-0019

March 14, 1989

Rep. Ron Wyden
Suite 1406
Longworth House Office Bldg.
Washington, D.C. 20515

RE: IVF/GIFT SURVEY
Subcommittee Hearings

Dear Representative Wyden:

Thank you for forwarding a facsimile of the survey of IVF clinics which was taken by your subcommittee on Regulation and Business Opportunities.

The survey was apparently taken over the phone and we have noted a number of inaccuracies regarding the statistics for our institution, the Robert Wood Johnson Medical School. Mark Balkin was kind enough to take the following correct values over the phone:

		Incorrect	Correct
Stimulation Cycles	'87 IVF	130	128
Stimulation Cycles	'88 IVF	226	182
Live Births	'87 IVF	5	9

I would greatly appreciate a confirmation that these changes have been made and whether they will be reflected in your subcommittee's final report.

Thank you for your cooperation.

Sincerely,

Ekkehard Kemmann, M.D.
Division, Reproductive Endocrinology
and Infertility

mrp

UMD
NEW JERSEY
University of Medicine & Dentistry of New Jersey
Robert Wood Johnson Medical School

Department of Obstetrics & Gynecology
Division of Reproductive Endocrinology-Infertility
201/937-7627

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New Brunswick, New Jersey, 08903-0019

March 21, 1989

Rep. Ron Wyden
Chairman, Subcommittee on
Regulation and Businss Opportunities
Suite 1408
Longworth House Office Building
Washington, DC 20515

RE: **REPORT ON IVF FACILITIES**

Dear Mr. Chairman:

The congressional subcommittee has recently released the findings of a survey taken on facilities offering in vitro fertilization (IVF) and gamete intra-fallopian transfer (GIFT). While we commend the Congress for attempting to evaluate program statistics and success rates, we are seriously concerned about the methodology employed by the survey and the potential implications.

Of major concern is the method used to derive "success rate" as subsequently reported in the media. Most IVF facilities base their statistics on patients who have undergone ovum retrieval. Indeed, it is not until the retrieval stage that an IVF cycle defers significantly from other standard infertility therapies. This survey, however, has elected to use "stimulation cycles started" as the primary denominator.

This approach presents several problems:

1. **Effect Upon Patient Selection:**

Unfortunately, the survey made no inquiry regarding the diversity of patient populations among different facilities and did not attempt to differentiate between IVF facilities which service patients with difficult ovarian stimulation. For example, our program had accepted patients ages 40 and over and allowed them to begin a stimulation cycle as a test of their ovarian response. Our intention was to determine which patients should undergo the actual in vitro process based on individual, physiological criteria, rather than more rigid age limits. Furthermore, we take great pains to fine-tune medication regimens to achieve a "good" stimulation cycle in younger patients with poor ovarian

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response. We may analyze even more than one month of treatment before we achieve sufficient, promising ovum development to warrant putting a patient through the operative process. Nevertheless, a program such as ours must include these medication trials along with treatment cycles which actually result in the operative process in determining our success rate. Yet, we are not differentiated statistically from those programs which simply perform the operative procedure on unproblematic patients. Comparing round figures from our institution with those of a facility which only services "easy" patients or patients who have only tubal constraints is in effect comparing the proverbial apples and oranges.

If the subcommittee's report becomes a benchmark for evaluating IVF programs, it will discourage the use of individual physiological criteria in favor or strict age cut-offs and it will reflect harshly on programs which elect to accept difficult cases.

2. **False Impression on the Cost of IVF Treatment:**

The survey's focus on stimulated cycles gives the false impression that all patients who initiate ovarian stimulation incur the burdensome charges of a complete IVF cycle. While costs for the complete IVF treatment ranges from $4,000 to $7,000, the cost of a cycle initiated but not progressing to ovum retrieval is relatively minor. For example, a patient may discontinue treatment on day 3 of her cycle at a cost of less than $100. Even patients who drop out shortly before an anticipated retrieval incur a cost of only several hundred dollars, just a fraction of the expense of a completed IVF cycle. In fact, pre-retrieval costs are in effect only those charges standard incurred for standard, non-IVF infertility therapy. Furthermore, in programs like our own, no professional fee is charged to patients whose cycles do not progress to ovum retrieval.

3. **IVF Stimulation Cycles Overlap With Alternative/Backup Treatment:**

When the survey was taken, the congressional staffers seemed to be unclear on exactly which treatment cases and procedures fall under the rather vaguely defined categories. For example, the fertility literature and our own experience has documented patients who start an IVF-intended ovarian stimulation and conceive without going through retrieval and in vitro fertilization. Clearly, we cannot count them as an IVF success, yet under this accounting system, these pregnancies will actually be counted against our program performance!

In the majority of IVF indications, super-ovulation with intrauterine insemination (IUI) remains an alternative or back-up treatment choice. The treatment is essentially identical until hCG administration. Commonly, utilizing the data developed in the individual stimulation cycle, patients and the physician decide jointly whether to proceed to retrieval or utilize IUI. Utilizing stimulation cycles as the benchmark for success compromises the operational flexibility which we have developed.

4. **Promoting the Use of GNRHa (Lupron):**

The emphasis on initiated treatment cycles will spur programs to utilize GNRHa extensively to suppress endogenous pituitary interference. While some patients seem to benefit from this approach, it remains entirely unclear that all patients need this costly and often painful approach. Nevertheless, because this is an effective method of reducing the percentage of stimulation cycles which will not go to retrieval, it will boost the success rate as calculated in your survey. Thus, your choice of denominator will predictably enhance the use of this costly, experimental medication for induction cycles merely as a cosmetic exercise to polish the data without clear evidence of benefit as measured by pregnancies per retrieval.

It is for good reasons, therefore, that medical professionals in general have favored pregnancies per patients undergoing ovum retrieval in determining the success rate for in vitro fertilization. It is widely acknowledged that ovum retrieval launches the actual in vitro segment, effects a medically invasive procedure, and generates the greatest risk, discomfort and the bulk of laboratory work and expense. The subcommittee's choice of denominator will have an important potential impact upon therapy and patient management. Therefore, we strongly encourage the subcommittee to reconsider the equation it is using to determine the success rate for in vitro fertilization. In addition, because of the precarious nature of the variable "ongoing pregnancies", we encourage the biannual update of survey information for IVF facilities.

Sincerely,

Ekkehard Kemmann, M.D.
Director, Divison of Reproductive
Endocrinology-Infertility

mrp
SUBCOMM

IVF/GIFT SURVEY

CLINIC NAME: PRESRYTERIAN HOSPITAL IN VITRO FERTILIZATION PROGRAM
ADDRESS: 201 Cedar SE. # 307
ALBUQUERQUE, NEW MEXICO 87106

CONTACT PERSON: JIM THOMPSON MD
PHONE NUMBER: (505) 247-3333

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    - (a) Private ______
    - (b) Community hospital based X
    - (c) University based ______
    - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1 (same physicians as above)

6. How many other professionals participate in your clinic?
    - (a) Physicians ______
    - (b) Laboratory Scientists (PhDs) ______
    - (c) Nurses 1
    - (d) Embryo Lab Technicians/Technologists 1
    - (e) Other Lab Technicians/Technologists ______
    - (f) Radiology (Ultrasound) Technicians ______
    - (g) Psychologists/Counselors 1
    - (h) Secretaries 1
    - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 1½

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1987 GIFT 1987

9. How many different patients were stimulated?
1987 IVF ____ 1988 IVF 20
GIFT ____ GIFT 14

10. How many stimulation cycles were performed?
1987 IVF ____ 1988 IVF 34
GIFT ____ GIFT 17

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ____ 1988 29* IVF only procedures.

How many embryo transfer cycles were performed?
1987 ____ 1988 27**

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ____ 1988 16

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:

Since some patients have multiple problems, the percentages do not equal 100%.

(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF 19 95%
GIFT ___ ___% GIFT 3 21%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 1 5%
GIFT ___ ___% GIFT 4 29%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 1 5%
GIFT ___ ___% GIFT 4 29%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF 0 0%
GIFT ___ ___% GIFT 2 14%
(e) Other (explain): antibodies, ovulation, adhesions, fibroids
1987 IVF ___ ___% 1988 IVF 0 0%
GIFT ___ ___% GIFT 4 29%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF 9 45%
GIFT ___ ___% GIFT 3 21%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF 5 25%
GIFT ___ ___% GIFT 4 29%
(c) 36-40:
1987 IVF ___ ___% 1938 IVF 6 30%
GIFT ___ ___% GIFT 7 50%

* In 1988 our clinic also performed 15 IVF/GIFT combination procedures in 1988 for a total of 44 retrievals thru 11/88.

** IVF only procedures. ~~Our clinic~~ embryo transfers. Our Clinic also performed 13 additional embryo transfers following IVF/GIFT combinations for a total of 40 Embryo transfers thru 11/88.

(d) 41-45:
1987 IVF ___ ___% 1988 IVF 0 0 %
GIFT ___ ___% GIFT 0 0 %

(e) >45:
1987 IVF ___ ___% 1988 IVF 0 0 %
GIFT ___ ___% GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF ___ 1988 IVF 5
GIFT ___ GIFT 7

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 thru IVF 1
GIFT ___ GIFT 4

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 4
GIFT ___ GIFT 3

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF 0
GIFT ___ GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% __________
GIFT ___ ___% __________

1988 IVF 1 20 % one triplet birth
GIFT ___ ___% __________

21. What are the qualifications of the director of the embryo laboratory? Reproductive Endocrine & Fellowship; Extensive IVF lab experience, Research in Mouse Embryo Assay. Attended 5 post graduate courses, including IVF laboratory course (Norfolk) Va, Reno, Nevada

22. Who supervises the laboratory director? Self

23. Does the clinic participate in an external laboratory proficiency testing program? Had an on-site laboratory visit by Dr. David Meldrum (from Los Angeles)
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Currently Applying for membership. (We have submitted data)

27. Does the clinic train individuals in IVF or GIFT? NO
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ________
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Our clinic deals with a small patient volume due to New Mexico's sparse population. We have been successful with both GIFT and IVF, adhere to high standards, and give realistic prognosis is to patients. We have a single Reproductive Endocrinologist who personally performs all the surgeries, and one lab technologist/embryologist who works with laboratory culture of oocytes.

IVF/GIFT SURVEY

CLINIC NAME: DEPT OB GYN
ADDRESS: CHILDRENS HOSPITAL OF BUFFALO
140 HODGE AVE
Buffalo, NY 14222

CONTACT PERSON: KENT CRICKARD MD DIRECTOR
PHONE NUMBER: (716) 878-7695

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the never clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/9/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   - (a) Physicians ______
   - (b) Laboratory Scientists (PhDs) ______
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 1 (PhD)
   - (e) Other Lab Technicians/Technologists ______
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors ______
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 8 months

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1986 (4 months) GIFT 1986 (one cycle)
(under a different director).
The clinic was reopened in 1988 under present director

9. How many different patients were stimulated?
1987 IVF 0 1988 IVF 24
GIFT 0 GIFT 10

10. How many stimulation cycles were performed?
1987 IVF 0 1988 IVF 30
GIFT 0 GIFT 12

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 0 1988 22

How many embryo transfer cycles were performed?
1987 0 1988 20

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 10

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0% 1988 ___100%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 0 ___% 1988 IVF 18 75%
GIFT 0 ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF 0 ___% 1988 IVF 2 8%
GIFT 0 ___% GIFT 2 20%
(c) Male infertility:
1987 IVF 0 ___% 1988 IVF 1 4%
GIFT 0 ___% GIFT 0 ___%
(d) Unexplained infertility:
1987 IVF 0 ___% 1988 IVF 2 8%
GIFT 0 ___% GIFT 6 60%
(e) Other (explain): MALE + OVULATORY DISORDER)
1987 IVF 0 ___% 1988 IVF 1 4% ←
GIFT 0 ___% GIFT 2 20% ← (Failed ovulation induction for ovulatory problems)

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 ___% 1988 IVF 1 4%
GIFT 0 ___% GIFT 0 0%
(b) 31-35:
1987 IVF 0 ___% 1988 IVF 14 58%
GIFT 0 ___% GIFT 7 70%
(c) 36-40:
1987 IVF 0 ___% 1988 IVF 6 25%
GIFT 0 ___% GIFT 2 20%

(d) 41-45:
1987 IVF 0 ___% 1988 IVF 3 13%
GIFT 0 ___% GIFT 1 10%

(e) >45:
1987 IVF 0 ___% 1988 IVF 0 0%
GIFT 0 ___% GIFT 0 0%

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___% ___
GIFT 0 ___% ___

1988 IVF 0 ___% ___
GIFT 0 ___% ___

21. What are the qualifications of the director of the embryo laboratory? BOARD CERTIFIED REPRODUCTIVE ENDOCRINOLOGIST

22. Who supervises the laboratory director? Dr K. CRICKARD DIRECTOR IVF PROGRAM

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
However, outside embryologist has reviewed our program during operation.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

1. Two patients undergoing embryo transfer procedures have been through previous IVF procedures at other programs including the use of frozen embryos in one case

2. Two patients who went through two embryo transfer cycles each had uterine anomalies.

IVF/GIFT SURVEY

CLINIC NAME: Albert Einstein College of Medicine Fertility and Hormone Center
ADDRESS: 88 Ashford Avenue
Dobbs Ferry, NY 10522

CONTACT PERSON: Michael Feinman, M.D.
PHONE NUMBER: (914) 693-8820

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/15/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based ______
   (c) University based off-campus out-patient center
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   (a) Physicians 1
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 2
   (d) Embryo Lab Technicians/Technologists 1
   (e) Other Lab Technicians/Technologists 2
   (f) Radiology (Ultrasound) Technicians ______
   (g) Psychologists/Counselors 1
   (h) Secretaries 2
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 2.5

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 5/86 GIFT 12/86

9. How many different patients were stimulated?
1987 IVF 37 1988 IVF 40
GIFT 29 GIFT 33

10. How many stimulation cycles were performed?
1987 IVF 67 1988 IVF 67
GIFT 45 GIFT 42

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 47 1988 55

How many embryo transfer cycles were performed?
1987 32 1988 40

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 33 1988 35

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 12 16%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 24 37.5% 1988 IVF 30 42.2%
GIFT 4 6.3 % GIFT 6 8.5 %
(b) Endometriosis:
1987 IVF 4 6.3 % 1988 IVF 6 8.5 %
GIFT 8 12.5 % GIFT 5 7.0 %
(c) Male infertility:
1987 IVF 1 1.5 % 1988 IVF 3 4.2%
GIFT 5 7.8 % GIFT 6 8.5 %
(d) Unexplained infertility:
1987 IVF 5 7.8% 1988 IVF 0 0 %
GIFT 11 17.2 % GIFT 11 15.5%
(e) Other (explain): immunological factors, ovarian cyst, pre-mature menopause, T-shaped uterus
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 2 3.1 % GIFT 4 5.6 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 9 14.1% 1988 IVF 8 11.3%
GIFT 8 12.5% GIFT 7 9.9 %
(b) 31-35:
1987 IVF 19 29.7% 1988 IVF 17 23.9%
GIFT 13 20.3% GIFT 11 15.5%
(c) 36-40:
1987 IVF 5 7.8% 1988 IVF 13 18.3%
GIFT 6 9.4 % GIFT 9 12.7%

(d) 41-45:
1987 IVF 3 4.7 % 1988 IVF 1 1.4 %
GIFT 1 1.5 % GIFT 4 5.6 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 1 1.4 %

16. How many clinical pregnancies were produced?
1987 IVF 3 1988 IVF 6
GIFT 11 GIFT 7

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 2 1988 IVF 0
GIFT 11 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 2 1988 IVF 6
GIFT 11 GIFT 5

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___ % ______
GIFT 1 .9 % Twins
1988 IVF 0 ___ % ______
GIFT 0 ___ % ______

Note: Some twin gestations are currently on-going.

21. What are the qualifications of the director of the embryo laboratory? M.D. 1 year prior experience at another institution.

22. Who supervises the laboratory director? Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? No - not aware of one.
If the answer is yes, please specify which program.
______

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ______
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ______
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

We accept women over 40 years of age and previously documented poor responders. This may adversely affect our pregnancy rate.

IVF/GIFT SURVEY

CLINIC NAME: Program of In Vitro Fertilization
ADDRESS: The Center for Reproductive Medicine anddInfertility
The New York Hospital- Cornell Medical Center
Box 1 525 East 68th Street
New York, N.Y. 10021
CONTACT PERSON: Zev Rosenwaks, M.D. Director
PHONE NUMBER: 212-746-1762

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the never clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12.2.88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ____
   (b) Community hospital based ____
   (c) University based XX
   (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
   (a) Physicians 0
   (b) Laboratory Scientists (PhDs) 4
   (c) Nurses 4
   (d) Embryo Lab Technicians/Technologists 3
   (e) Other Lab Technicians/Technologists 3
   (f) Radiology (Ultrasound) Technicians ____
   (g) Psychologists/Counselors 1
   (h) Secretaries 3
   (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? 2

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 1/87 GIFT 1/87

1/1/88 - 6/30/88 7/1/88 - 12/2/88.

9. How many different patients were stimulated?

1987 IVF 110 1988 IVF 122 120

GIFT 27 GIFT 14 5

10. How many stimulation cycles were performed?

1987 IVF 175 1988 IVF 153 160

GIFT 30 GIFT 26 5

11. For those clinics offering IVF:
How many egg recovery procedures were performed?

1987 116 1988 121 123

How many embryo transfer cycles were performed?

1987 107 1988 113 98

12. How many GIFT procedures (attempted egg recoveries) were performed?

1987 30 1988 21 3

13. What were the number and percentage of patients on IRB approved research protocols?

1987 0 0% 1988 0 0%

14. What were the number and percentage of patients treated for:

(a) Tubal factor:

1987 IVF 71 41% 1988 IVF ___ __%

GIFT 0 0% GIFT ___ ___%

(b) Endometriosis:

1987 IVF 36 20% 1988 IVF ___ ___%

GIFT 4 13 % GIFT ___ ___%

(c) Male infertility:

1987 IVF 21 12% 1988 IVF ___ ___%

GIFT 3 10 % GIFT ___ ___%

(d) Unexplained infertility:

1987 IVF 24 14% 1988 IVF ___ ___%

GIFT 23 77 % GIFT ___ ___%

(e) Other (explain): PCO, mixed diagnoses, etc.

1987 IVF 23 13% 1988 IVF ___ ___%

GIFT 0 0 % GIFT ___ ___%

1988 - [illegible] male factors

15. What were the number and percentage of patients in the following age groups:

(a) <31:

1987 IVF 37 21% 1988 IVF 20 13% 33 20%

GIFT 3 10 % GIFT 2 8% 0 0%

(b) 31-35:

1987 IVF 58 33% 1988 IVF 60 39% 75 47%

GIFT 10 33 % GIFT 8 30 % 3 60%

(c) 36-40:

1987 IVF 71 41% 1988 IVF 60 39% 58 33%

GIFT 10 33 % GIFT 10 38 % 0 0%

7.1.88 - 12.2.88

(d) 41-45:
1987 IVF 9 5 % 1988 IVF 13 9 % / 37 22%
GIFT 7 23 % GIFT 6 24 % / 0 0%

(e) >45: Do not treat this age group
1987 IVF ___ ___ % 1988 IVF ___ ___ %
GIFT ___ ___ % GIFT ___ ___ %

16. How many clinical pregnancies were produced? 7/1 → 12/2/88
1987 IVF 17 1988 IVF 11 / 19
GIFT 7 GIFT 4 / 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 13 1988 IVF 2 / 0
GIFT 4 GIFT 3 / 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 6 / 18
GIFT 0 GIFT 1 / 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0 / 1
GIFT 0 GIFT 0 / 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 4 30 % 3 sets twins, 1 set triplets
GIFT 1 25 % 1 set twins

1988 IVF 1 50 % 1 set triplets
GIFT 1 33 % 1 set twins

21. What are the qualifications of the director of the embryo laboratory? World expert in gamete physiology

22. Who supervises the laboratory director? Dr. Rosenwaks

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
Outside experts are periodically asked to critique the endocrine and embryology laboratories.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Approval is pending. Dr. Rosenwaks has previously directed the Norfolk Reproductive Medicine program.

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** Yes

27. **Does the clinic train individuals in IVF or GIFT?** Yes **If the answer is yes, how many individuals in the following specialties have been trained?**
    - **(a) Physicians** 2
    - **(b) Laboratory scientists (PhDs)** 1
    - **(c) Embryo laboratory technicians/technologists** 2
    - **(d) Nurses** 2
    - **(e) Other (explain)** ________

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

As a tertiary IVF clinic, we accept many patients referred from other major IVF clinics. Many of these patients have failed at other clinics.

More importantly, Manhattan's older female population at the time IVF is tried, makes the proportion of over 40 somewhat higher as our clinic matures.

525 EAST 68th STREET, NEW YORK, N.Y.
THE NEW YORK HOSPITAL-CORNELL MEDICAL CENTER

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY

January 3, 1989

Congressman Ron Wyden
Chairman,
Subcommittee on Regulation
& Business Opportunities
House of Representatives
Congress of the United States
Suite 1406
Longworth House Office Building
Washington, DC 20515

Dear Congressman Wyden:

As per your letter of 11/11/88, enclosed are the recent statistics of the Cornell In Vitro Fertilization Program. You will note that the results of 1988 are presented in two sections. The first six months followed by the second six months. This is to reflect the changes that have been implemented at the Cornell clinic since my arrival.

Let me assure you that as one of the physicians who wrote the commentary in the November, 1987 Fertility and Sterility I am extremely anxious that infertility practice be of the highest clinical and moral standards.

As the former Director at The Jones Institute For Reproductive Medicine and its In Vitro Fertilization program, I have always felt that accurate reporting of results and patient awareness is essential. I am also cognizant of the fact that results often reflect the particular patient population treated, as well as, the expertise of a particular clinic.

Thus, I urge you to carefully evaluate the compounding factors, namely, age of patient, factor of infertility, number of attempts at IVF and ovarian response to stimulation when gathering and reporting IVF and GIFT results.

I wish you success in this most important endeavor.

If there is any other information you may need, please do not hesitate to let me know.

With warmest regards.

Sincerely,

Zev Rosenwaks, M.D.
Director,
The Center for Reproductive
Medicine & Infertility
Professor of [illegible]
Gynecology

ZR:dc

THE CENTER FOR REPRODUCTIVE MEDICINE
AND INFERTILITY
CORNELL UNIVERSITY MEDICAL COLLEGE
DEPARTMENT OF OBSTETRICS AND GYNECOLOGY
505 EAST 70th STREET, NEW YORK, NY 10021 • (212) 746-1745

Zev Rosenwaks, M.D., Director
Professor, Obstetrics and Gynecology

March 14, 1989

Honorable Congressman Ron Wyden
Chairman,
Subcommittee on Regulation &
Business Opportunities
House of Representatives
Congress of the United States
Suite 1406
Longworth House Office Building
Washington, DC 20515

Dear Congressman Wyden:

Your recent release of the In Vitro Fertilization clinics' statistics, although presented with the best intentions, has done a disservice to the public in the New York area and to the New York Hospital-Cornell In Vitro Fertilization Program. When we provided you with our recent statistics for 1988, the results were specifically segregated to reflect the recent changes in staff and protocols at Cornell.

The cumulative 1987 or 1988 statistics do not represent the State-of-the-Art of In Vitro Fertilization at New York Hospital. Thus, I am providing you with an update of the results of the Cornell Clinic since my full-time arrival at Cornell (to be included in the report). Keep in mind that our population of patients often represent "failed" referrals from other In Vitro Fertilization Clinics, often women over the age of 40 (22%) and a significant proportion of male factor infertility patients.

Despite this remarkable array of "poor" candidates, who are carefully informed of their potential "poor" outcome, our results have been better than those reflected and mentioned in your report.

The following represent an update of our recent statistics since the changes in staff were made.

Stimulated (started) cycles	Oocyte Retrievals	Embryo Transfer	Ongoing Pregnancies
236	172	142	31

Pregnancy rates:

31/236 = 14% per stimulated cycle	31/172 = 18% per retrieval	31/142 = 22% per transfer

Since we are in a unique position, in terms of the recent changes in staff and expertise, our results should be presented to reflect the present success expectation.

It is with the patient's interest in mind and in a cooperative spirit that we forward these results to you with the hope that they will be made available to the public in your upcoming report.

Thank you.

Yours sincerely,

Zev Rosenwaks

Zev Rosenwaks, M.D.
Director,
The Center For Reproductive Medicine & Infertility
Professor,
Obstetrics and Gynecology

ZR:dc
attachment
cc: Warren E. Leary

IVF/GIFT SURVEY

CLINIC NAME: Wayne H. Decker IVF Program
ADDRESS: 1430 Second Avenue
New York, NY 10021

CONTACT PERSON: Maurice Goldstein
PHONE NUMBER: (212) 744-5500

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/12/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based
   - (c) University based
   - (d) Other (explain)

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
   - (a) Physicians ✓
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 3
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 1
   - (h) Secretaries ✓
   - (i) Other (specify) Clinical Administrator

7. How many years has your infertility clinic been in operation? 22

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 4/87 GIFT None

9. How many different patients were stimulated?
1987 IVF 10 1988 IVF 37
GIFT [illegible] GIFT X

10. How many stimulation cycles were performed?
1987 IVF 15 1988 IVF 53
GIFT — GIFT —

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 11 1988 37

How many embryo transfer cycles were performed?
1987 9 1988 32

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 — 1988 —

13. What were the number and percentage of patients on IRB approved research protocols?
1987 NA ___% 1988 NA ___%

14. What were the number and percentage of patients treated for:
   (a) Tubal factor:
      1987 IVF (8) 80 % 1988 IVF (24) 65 %
      GIFT — — % GIFT — — %
   (b) Endometriosis:
      1987 IVF (2) 20 % 1988 IVF (4) 11 %
      GIFT — — % GIFT — — %
   (c) Male infertility:
      1987 IVF (1) 10 % 1988 IVF (11) 30 %
      GIFT — — % GIFT — — %
   (d) Unexplained infertility:
      1987 IVF (1) 10 % 1988 IVF (10) 27 %
      GIFT — — % GIFT — — %
   (e) Other (explain): Ovarian
      1987 IVF (1) 10 % 1988 IVF (1) 3 %
      GIFT — — % GIFT — — %

15. What were the number and percentage of patients in the following age groups:
   (a) <31:
      1987 IVF (4) 40 % 1988 IVF (5) 13 %
      GIFT — — % GIFT — — %
   (b) 31-35:
      1987 IVF (3) 30 % 1988 IVF (14) 38 %
      GIFT — — % GIFT — — %
   (c) 36-40:
      1987 IVF (2) 20 % 1988 IVF (14) 38 %
      GIFT — — % GIFT — — %

(d) 41-45:
1987 IVF (1) 10 % 1988 IVF (4) 11 %
GIFT – ___ % GIFT – ___ %

(e) >45:
1987 IVF – – % 1988 IVF – – %
GIFT – – % GIFT – – %

16. How many clinical pregnancies were produced?
1987 IVF 2 1988 IVF 5
GIFT – GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF – 1988 IVF 1
GIFT – GIFT –

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF – 1988 IVF 4
GIFT – GIFT –

19. How many ectopic pregnancies resulted?
1987 IVF – 1988 IVF –
GIFT – GIFT –

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF – ___ % –
GIFT – ___ % ___

1988 IVF – ___ % –
GIFT ___ ___ % ___

21. What are the qualifications of the director of the embryo laboratory? Dr. Kadam Ph.D in Cell Biology

22. Who supervises the laboratory director? Wayne H. Decker, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? no
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** yes

27. **Does the clinic train individuals in IVF or GIFT?** yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) **Physicians** 3
    (b) **Laboratory scientists (PhDs)** 1
    (c) **Embryo laboratory technicians/technologists** 2
    (d) **Nurses** 2
    (e) **Other (explain)** Administrator

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

Ours is a small private clinic, which has been treating infertility by traditional means for twenty-two years. In mid 1987, we added IVF facilities in order to treat patients who had not succeeded in becoming pregnant by any other means. We continue to treat the majority of our patients by the older methods.

Our small volume of IVF patients allows us to treat each one with personal, one-on-one care.

IVF/GIFT SURVEY

CLINIC NAME: LIFE PROGRAM
ADDRESS: ALBANY MEMORIAL HOSPITAL
600 NORTHERN BLVD.
ALBANY, NEW YORK 12204

CONTACT PERSON: EDGAR S. HENRIQUES, M.D., FRCS(C)
PHONE NUMBER: (518) 482-1007

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/15/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified ~~and/or Board Eligible~~ Reproductive Endocrinologists participate in your clinic? ONE

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? NONE AT PRESENT DIRECTLY

6. How many other professionals participate in your clinic?
   - (a) Physicians ONE
   - (b) Laboratory Scientists (PhDs) THREE
   - (c) Nurses FIVE
   - (d) Embryo Lab Technicians/Technologists TWO
   - (e) Other Lab Technicians/Technologists ______
   - (f) Radiology (Ultrasound) Technicians ONE
   - (g) Psychologists/Counselors ON CALL
   - (h) Secretaries TWO
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 8 MONTHS

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF MAY 1988 GIFT MAY 1988

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF 11
GIFT ______ GIFT 1

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF 15
GIFT ______ GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ________ 1988 15

How many embryo transfer cycles were performed?
1987 ________ 1988 12

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ________ 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF 9 82%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT 1 9%
(e) Other (explain): PCO
1987 IVF ___ ___% 1988 IVF 1 9%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF 4 36%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF 5 45%
GIFT ___ ___% GIFT 1 9%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF 1 9%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF ___ 1988 IVF 1
GIFT ___ GIFT ___ WAITING ON ONE

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF 0
GIFT ___ GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 0
GIFT ___ GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF 0
GIFT ___ GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ______________
GIFT ___ ___% ______________

1988 IVF ___ 0 % ______________
GIFT ___ 0 % ______________

21. What are the qualifications of the director of the embryo laboratory? Ph.D. Reproductive Endocrinology with 25 YRS research experience in Reproduction

22. Who supervises the laboratory director? Hospital Director and Clinical Director

23. Does the clinic participate in an external laboratory proficiency testing program? YES
If the answer is yes, please specify which program.
N.Y. State Dept. of Health Proficiency Testing in Endocrinology Chemistry

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? NO

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ✓
    (b) Laboratory scientists (PhDs) ✓
    (c) Embryo laboratory technicians/technologists ✓
    (d) Nurses ____
    (e) Other (explain) P.A.

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

EDGAR S. HENRIQUES, M.D., F.R.C.S. (C.), F.A.C.O.G.
REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY

REGINA MATTIES, R.N.C., M.S.
Clinical Nurse Specialist

The LIFE program at the Memorial Hospital Albany, New York has been the first of its kind in the area serving over 2 million people. Dr. Edgar S. Henriques, who is the Medical Director of the program is a former Professor and the Head of the Division of Reproductive Endocrinology at the Albany Medical College and the first and the only practicing Board-Certified Reproductive Endocrinologist in the region until 1987.

Regina Matties, R.N.C., M.S. is the IVF nurse coordinator. She has worked with Reproductive Endocrinology and Infertility since 1977. Denise Spor, R.N. has been involved with the IVF program since the planning stage. She maintains our continuity with the patients from the office to [illegible] operating room by participation [illegible] retrieval [illegible] transfer.

The program is actively supported by the laboratory staff which includes Dr. Sharad Joshi, who also serves as the co-director of the program, two assistant directors (one Reproductive Endocrinologist and one Embryologist both at the Ph.D. level) and two technologists.

The program goals are not only to [illegible] newer reproductive technologies to infertile couples at the lowest possible cost but, also to undertake research and education in the field of infertility. The three Ph.D. level laboratory staff members hold joint appointments with the State University of New York and the Albany Medical College. Dr. Joshi who is credited with the discovery of a unique endometrial protein designated Progesterone-Dependent Endometrial Protein or PEP (for which he was awarded a U.S. patent) is actively involved in N.I.H. supported basic and clinical research on the human endometrial function during infertility and pregnancy failure. Such research is being undertaken in collaboration with some of the worlds leading investigators in the infertility field. The LIFE program at the Memorial Hospital in Albany is relatively new and therefore it is premature to arrive at the success or failure rate. However, we are quite encouraged by the fact that our rates of oocyte fertilization and cleavage are well above the national average.

980 WESTERN AVENUE, ALBANY, N.Y. 12203 (518) 482-1007

1st

IVF/GIFT SURVEY

CLINIC NAME: The In Vitro Fertilization Program
ADDRESS: Mount Sinai Medical Center
1212 Fifth Avenue, Box 1175
New York, NY 10029

CONTACT PERSON: Daniel Navot, M.D.
PHONE NUMBER: (212) 241-5927

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based ______
   (c) University based X
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   (a) Physicians 5
   (b) Laboratory Scientists (PhDs) 2
   (c) Nurses 5
   (d) Embryo Lab Technicians/Technologists 2
   (e) Other Lab Technicians/Technologists 1
   (f) Radiology (Ultrasound) Technicians 1
   (g) Psychologists/Counselors 1
   (h) Secretaries 2
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 2 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF Dec. 1986 GIFT July 1987

9. How many different patients were stimulated?
1987 IVF 123 1988 IVF 210
GIFT 18 GIFT 51

10. How many stimulation cycles were performed?
1987 IVF 261 1988 IVF 311
GIFT 18 GIFT 72

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 193 1988 330

How many embryo transfer cycles were performed?
1987 180 1988 264

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 18 1988 63

13. What were the number and percentage of patients on IRB approved research protocols?
1987 23 8.2% 1988 71 18.5%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF * ___% 1988 IVF 200 60.9%
GIFT * ___% GIFT 4 6.6 %
(b) Endometriosis:
1987 IVF * ___% 1988 IVF 23 6.4 %
GIFT * ___% GIFT 8 10.5%
(c) Male infertility:
1987 IVF * ___% 1988 IVF 37 18.7%
GIFT * ___% GIFT 20 31.6 %
(d) Unexplained infertility:
1987 IVF * ___% 1988 IVF 15 4.2 %
GIFT * ___% GIFT 36 47.4%
(e) Other (explain): Immunological; DES, Cervical, Ovarian Failure
1987 IVF * ___% 1988 IVF 36 9.8 %
GIFT * ___% GIFT 4 3.9 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF * ___% 1988 IVF 42 13.5%
GIFT * ___% GIFT 8 11.1 %
(b) 31-35:
1987 IVF * ___% 1988 IVF 122 39.2%
GIFT * ___% GIFT 22 30.5 %
(c) 36-40:
1987 IVF * ___% 1988 IVF 127 40.8%
GIFT * ___% GIFT 34 47.2%

* Not available for 1987

(d) 41-45:
1987 IVF * ___% 1988 IVF 18 5.8 %
GIFT * ___% GIFT 10 13.9 %

(e) >45:
1987 IVF * ___% 1988 IVF 2 0.6 %
GIFT * ___% GIFT — — %

16. How many clinical pregnancies were produced?
1987 IVF 29 1988 IVF 45
GIFT 6 GIFT 28

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 21 1988 IVF 9
GIFT 4 GIFT 7

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF none 1988 IVF 21
GIFT none GIFT 12

19. How many ectopic pregnancies resulted?
1987 IVF 2 1988 IVF 2
GIFT 0 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 8 38 % 7 twins, 1 triplet
GIFT 1 25 % 1 set of twins

1988 IVF 3 34 % 3 sets of twins
GIFT 3 43 % 3 sets of twins

21. What are the qualifications of the director of the embryo laboratory? Ph.D. with post doctoral training in embryology and micromanipulations.

22. Who supervises the laboratory director? Program Director - Daniel Navot, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program. ___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

* Not available for 1987

26. Is the clinic a member of the Society for Assisted Reproductive Technology? pending

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 12
    (b) Laboratory scientists (PhDs) 6
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses 10
    (e) Other (explain) _______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Remarks: Our clinic performs zona drilling as an experimental procedure for grave male infertility. Thirty four IVF and GIFT cycles were performed as part of the zona drilling protocol. On 14 occasions fertilization was attained despite failure to fertilize in previous IVF cycles. Those 34 attempts are excluded from the 1988 report.

IVF/GIFT SURVEY

CLINIC NAME: The In Vitro Fertilization Program
ADDRESS: Mount Sinai Medical Center
1212 Fifth Avenue, Box 1175
New York, NY 10029

CONTACT PERSON: Daniel Navot, M.D.
PHONE NUMBER: (212) 241-5927

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    - (a) Private ______
    - (b) Community hospital based ______
    - (c) University based X
    - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
    - (a) Physicians 5
    - (b) Laboratory Scientists (PhDs) 2
    - (c) Nurses 5
    - (d) Embryo Lab Technicians/Technologists 2
    - (e) Other Lab Technicians/Technologists 1
    - (f) Radiology (Ultrasound) Technicians 1
    - (g) Psychologists/Counselors 1
    - (h) Secretaries 2
    - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 2 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF Dec. 1986 GIFT July 1987

9. How many different patients were stimulated?
1987 IVF 129 1988 IVF 250
GIFT 12 GIFT 11

10. How many stimulation cycles were performed?
1987 IVF 267 1988 IVF 369
GIFT 12 GIFT 14

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 193 1988 330

How many embryo transfer cycles were performed?
1987 186 1988 319

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 12 1988 8

13. What were the number and percentage of patients on IRB approved research protocols?
1987 23 8.2% 1988 71 18.5%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF * ___% 1988 IVF 203 55.0%
GIFT * ___% GIFT 1 7 %
(b) Endometriosis:
1987 IVF * ___% 1988 IVF 29 7.9%
GIFT ___ ___% GIFT 2 14.3 %
(c) Male infertility:
1987 IVF * ___% 1988 IVF 53 14.4%
GIFT * ___% GIFT 4 28.6 %
(d) Unexplained infertility:
1987 IVF * ___% 1988 IVF 44 11.9%
GIFT * ___% GIFT 7 50 %
(e) Other (explain): Immunological; DES, Cervical, Ovarian Failure
1987 IVF * ___% 1988 IVF 40 10.8%
GIFT * ___% GIFT -- -- %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF * ___% 1988 IVF 48 13.0%
GIFT * ___% GIFT 2 14.3 %
(b) 31-35:
1987 IVF * ___% 1988 IVF 140 37.9%
GIFT * ___% GIFT 4 28.6 %
(c) 36-40:
1987 IVF * ___% 1988 IVF 154 41.7%
GIFT * ___% GIFT 7 50 %

*Not available for 1987

(d) 41-45:
1987 IVF * ___ % 1988 IVF 27 7.3 %
GIFT * ___ % GIFT 1 7 %

(e) >45:
1987 IVF * ___ % 1988 IVF 2 0.6 %
GIFT * ___ % GIFT -- --- %

16. How many clinical pregnancies were produced?
1987 IVF 29 1988 IVF 70
GIFT 6 GIFT 3

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 21 1988 IVF 33
GIFT 4 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF none 1988 IVF 31
GIFT none GIFT 2

19. How many ectopic pregnancies resulted?
1987 IVF 2 1988 IVF 2
GIFT 0 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 8 38 % 7 twins, 1 triplet
GIFT 1 25 % 1 set of twins

1988 IVF 11 33 % 11 sets of twins
GIFT 1 100 % 1 set of twins

21. What are the qualifications of the director of the embryo laboratory? Ph.D. with post doctoral training in embryology and micromanipulations

22. Who supervises the laboratory director? Program Director - Daniel Navot, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

* Not available for 1987

26. Is the clinic a member of the Society for Assisted Reproductive Technology? pending

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 12
    (b) Laboratory scientists (PhDs) 6
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses 10
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Remarks:

1. Our clinic performs zona drilling as an experimental procedure for grave male infertility. Thirty four IVF and GIFT cycles were performed as part of the zona drilling protocol. On 14 occasions fertilization was attained despite failure to fertilize in previous IVF cycles. Those 34 attempts are excluded from the 1988 report.
2. All patients that had combined IVF and GIFT procedures are reported as IVF.
3. Deliveries in 1988 include all the patients that delivered in 1988 and all ongoing pregnancies - gestational age of 5 month or older.
4. In section 11, numbers include embryo transfers and tubal transfers.

THE MOUNT SINAI IN VITRO FERTILIZATION PROGRAM
Department of Obstetrics, Gynecology and Reproductive Science
■
Dr. Daniel Navot, Director

April 12, 1989

Congressman Ron Wyden
CONGRESS OF THE UNITED STATES
House of Representatives
B363 Rayburn
House Office Building
Washington, DC 20515

Dear Congressman Wyden:

We have resubmitted our 1987/1988 program statistics. Mr. Balkin has requested explanations on our second submission.

All patients who have had a combined GIFT and IVF procedure were reported in the IVF statistics. The reason for this was to avoid bias that would misrepresent the true performance of our program. I have enclosed a recent publication in the Journal of the American Fertility Society in which the bias I am referring to is clarified. Namely, programs that perform IVF only achieve the highest success rate in patients with unexplained infertility. In programs that perform GIFT procedures, these same patients would have been candidates for GIFT. Respective pregnancy rates would be 37.3% in IVF compared to 24.5% with GIFT pregnancies excluded (Navot et al. Fertil Steril 49:854, 1988). Skimming off this very favorable sub-population will markedly diminish IVF pregnancy rates. For programs that have relatively low GIFT pregnancy rates this would not make any difference. However, in our program where GIFT pregnancy rates approach 50%, exclusion of them would misrepresent the actual quality care we are providing the population in need.

Our mutual goal is to give proper guidance to infertile patients seeking treatment. I believe that our statistics presented in this way better reflect the quality of care we are providing to our patients.

If there are any further question regarding the above, please feel free to contact my office.

Sincerely,

Navot

Daniel Navot, M.D.
Director
In Vitro Fertilization Program

Encl.
/jmc

The Mount Sinai Medical Center ■ One Gustave L. Levy Place, New York, N.Y. 10029

THE MOUNT SINAI IN VITRO FERTILIZATION PROGRAM
Department of Obstetrics, Gynecology and Reproductive Science
■
Dr. Daniel Navot, Director

March 22, 1989

Mr. Marc Balkin
CONGRESS OF THE UNITED STATES
House of Representatives
Washington, DC 20515

Dear Mr. Balkin:

As per our recent telephone conversation I am resubmitting the IVF Survey. It became apparent from discussing the matter with my colleagues at the meeting of the Society of Gynecologic Investigation that our way of presenting the data was inconsistent with the way in which my colleagues did it. It is needless to say that such a misrepresentation of the results does not only harm our credibility but also does a disservice to the patients by directing them to programs that are notoriously unsuccessful. This misguidance has unfortunately already taken place due to the article published in the New York Times. One of the highest scoring IVF programs mentioned in this article is actually a program that hardly ever produced a pregnancy.

Please implement the changes we have submitted and let me know if I can further clarify any of these very important issues.

Sincerely,

Daniel Navot

Daniel Navot, M.D.
Associate Professor
Director,
In Vitro Fertilization Program
Department of Obstetrics, Gynecology
and Reproductive Science

The Mount Sinai Medical Center ■ One Gustave L. Levy Place, New York, N.Y. 10029

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The value of in vitro fertilization for the treatment of unexplained infertility

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Suheil J. Muasher, M.D.
Sergio Oehninger, M.D.
Hung-Ching Liu, Ph.D.
Lucinda L. Veeck, M.L.T.
David Kreiner, M.D.
Zev Rosenwaks, M.D.

Eastern Virginia Medical School, The Jones Institute for Reproductive Medicine, Norfolk, Virginia

In 54 patients referred with the diagnosis of unexplained infertility (UI), the diagnosis was confirmed in 26 (strict UI) (48%). Minimal abnormalities (MA) were found in 19 (35%); 9 (17%) had gross abnormalities and were excluded from analysis. Fifty patients with tubal infertility were randomly assigned to form a control group. Mean age and type of stimulation did not differ in the two groups. Peak follicular estradiol (E_2) and terminal follicular E_2 patterns were comparable. There was no difference in the mean number of oocytes retrieved per cycle. However, the control group had significantly more preovulatory oocytes: 3.6 ± 2.0 standard deviations versus 2.8 ± 2.1 in the overall UI group (strict UI + MA groups) and 2.7 ± 2.2 in the strict UI group. Significantly more fertilized oocytes per cycle were obtained in the control group ($P < 0.05$). The per-cycle and per-embryo transfer (ET) pregnancy rates were 32.4 and 37.3% in the overall UI group and 24 and 24.5% in the control group. The miscarriage rate was 12% in the strict UI group, 22% in the overall UI group, and 25% in the control group. It is concluded that patients with UI constitute a favorable group for in vitro fertilization and ET. Fertil Steril 49:854, 1988

Patients with unexplained infertility (UI) comprise a heterogeneous group of an ill-defined population whose etiology of infertility remains elusive, despite a thorough infertility workup. The incidence of UI is about 10% to 15%,[1,2] the rate depending upon the strictness of criteria used for definition. UI should not be diagnosed unless at least 2 years of involuntary infertility, with regular intercourse, has been documented; and the female has proven ovulatory cycles (basal body temperature [BBT], serum progesterone [P], ultrasound), an adequate luteal phase (endometrial biopsy), normal uterus, patent tubes with no peritoneal factor (hysterosalpingogram, laparoscopy), normal cervical mucus production (cervical score, postcoital test), and a negative immunologic workup. The male partner must have a normal seminal fluid analysis, negative immunologic workup, and preferably a positive zona-free hamster egg/sperm penetration assay (SPA).[1-3] Treatment of UI is, by definition, experimental. It includes observation and reassurance,[4] augmentation of ovulation, artificial insemination by husband (AIH),[5] and antibiotic treatment for occult infection.[6] In vitro fertilization (IVF) is a novel approach for the treatment of UI.[7] Theoretically, IVF therapy can overcome or bypass occult abnormalities in the mechanism of tubal ovum pickup or tubal transport. It may prevent ovum entrapment, circumvent an offensive cervical mucus, and correct follicular phase abnormalities. The techniques involved in sperm preparation and oocyte handling could favorably affect autoimmune phenomena, and the favorable microenvironment and proximity of egg and sperm may enhance fertilization in an otherwise subfertile couple. Although IVF-embryo transfer (ET) has

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Received October 19, 1987; revised and accepted January 28, 1988.

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become an established treatment modality for various causes of infertility, its relative efficiency in treating UI has not been determined.[8-12]

This study was undertaken to establish the efficiency of IVF-ET for the treatment of UI by comparing the outcome to that of tubal infertility patients.

MATERIALS AND METHODS

From series 1-23 (February 1980 to July 1986), 54 patients were referred to the IVF program in Norfolk with the diagnosis of UI. UI is diagnosed only after at least 2 years of involuntary infertility with unprotected intercourse in the presence of ovulatory cycles (BBT, luteal phase serum P), normoprolactinemia, an adequate luteal phase (timed endometrial biopsy), normal pelvic anatomy (hysterosalpingogram, laparoscopy), and adequate cervical mucus production. Seminal fluid should be repeatedly within normal range (concentration $\geq 20 \times 10^6$/ml, motility $\geq$ 40%, and normal morphology $\geq$ 30%), and sperm/mucus interaction (postcoital test [PCT]) should not reveal any pathology. In the presence of spontaneous sperm agglutination, pathologic PCT, or a negative yield throughout the evaluation process, an immunologic workup of both partners is required.

In the 54 patients, completion of the infertility workup, including an augmented diagnostic laparoscopy, revealed major previously undetected abnormalities in 9, who were eventually excluded from the study. Five had overt peritoneal factors, 2 had mild to moderate endometriosis,[13] and 3 had clearly subfertile sperm. In 19 other patients, minimal abnormalities (MA) were detected (the MA group). Ten had focal—minimal—endometriosis, 1 had small subserous uterine myomata, and the rest had borderline sperm concentrations (16 to 20 $\times 10^6$/ml), history of pelvic surgery, very low titer antisperm antibodies, and genital tract malformations (2 patients in each category). In 26 referrals, diagnosis remained unchanged; these were designated the strict UI group. In the 45 patients, 67 IVF cycles were studied. In the strict UI group, 48 cycles were analyzed separately and also as part of the whole group of UI, which included 19 cycles of patients with MA.

Induction of multiple ovulation for IVF, monitoring technique, ovum pickup, and laboratory procedures were as described previously.[14-16]

Fifty cycles of 50 patients with infertility related to tubal factors were assigned as a control group by systematic random sampling. The number of tubal control patients randomly assigned from each series was similar to the number of study patients during the same time period. The two groups did not differ in age (35.7 ± 3.9 and 34.1 ± 3.5 in UI and controls, respectively). The type of ovarian stimulation, whether human menopausal gonadotropin (hMG), follicle-stimulating hormone (FSH), or a combination of these, was likewise similar in the two groups. Results are given as means ± standard deviation (SD). Statistical analysis was performed with the Student's t-test or the Fisher's exact test, as appropriate.

RESULTS

Table 1 details patient responses to induction of ovulation. Estradiol (E_2) levels on the day of human chorionic gonadotropin (hCG) administration (day 0) were remarkably similar in the overall UI group, the strict UI group, and controls. The majority of each group had a favorable (ascending) E_2 pattern, as apparent from E_2 values on day 0 and day +1 (Table 1). The mean number of follicles observed by ultrasonography on the day preceding ovum pickup was also comparable between the study groups and controls. The same was true for peak luteal phase progesterone (P). Oocyte quantity and quality are compared in Table 2. Significantly more preovulatory oocytes were harvested in controls than in the strict UI group or the overall UI group. The same trend held true for the mean number of preovulatory oocytes that fertilized per patient in controls versus the treatment groups (Table 2). In 4 of 48 cycles in the strict UI group, there was a complete failure of fertilization. The MA group contributed another cycle in which fertilization failed to occur, whereas only 1 of 50 cycles in controls had total fertilization failure. Failure of fertilization in all of these cycles could not be ascribed to any apparent abnormality of either eggs or sperm, specifically, preovulatory oocytes (metaphase I and II) had failed to fertilize. Despite the 4-fold increase in fertilization failure in the strict UI group compared with controls, the difference did not attain statistical significance (Table 2). No differences were observed among the three groups in the mean number of immature, atretic, or fractured zona oocytes. The outcome of IVF-ET is summarized in Table 3. Fertilization rates were slightly but not significantly lower in the UI group than in controls. Conception rates per cycle and per transfer compared favorably between UI patients and controls. The miscarriage rate was slightly (overall UI group) or appreciably (strict UI group) lower than in controls. The per transfer viable pregnancy rates (≥20 weeks of gestation) also

Table 1 Patient's Response to Induction of Ovulation (Unexplained Infertility versus Control [mean ± SD])

	No. of patients	No. of cycles	E_2 pattern: Mean E_2 day 0	E_2 pattern: Mean E_2 day 1	No. of follicles	Peak luteal progesterone
			pg/ml	*pg/ml*		*ng/ml*
Unexplained infertility (all)	45	67	687 ± 422	853 ± 508	7.8 ± 4.7	26 ± 18
Control	50	50	698 ± 410	922 ± 582	7.7 ± 3.0	23 ± 21
Unexplained infertility (strict)	26	48	715 ± 441	905 ± 579	7.6 ± 4.6	24 ± 27

compared in favor of the study population. None of the differences, however, attained statistical significance.

DISCUSSION

The diagnosis of UI is made by stepwise exclusion of any overt pathology; thus, the incidence of UI is inversely related to the thoroughness of the infertility workup. The relatively high incidence of undiagnosed gross abnormalities (17%) may be explained by the lag time between the basic infertility workup and re-evaluation in the IVF center. During that period, peritoneal adhesions might form (5 of 9; i.e., by hydrotubation, intrauterine inseminations), endometriosis might be acquired (2 of 9), and a previously normal seminal fluid analysis might become subfertile (3 of 9). The MA group could have had newly acquired pathologies, or they could have been missed. The presence of a few spots of endometriosis, a tiny subserous myoma, very low titer antisperm antibodies, or a history of ovarian cystectomy with no detectable subsequent pathology might still leave the infertility unexplained. Thus, we elected to analyze all UI patient cycles, including the MA group. For academic interest, we also analyzed the strict UI subgroup separately. The exclusion of patients with MA had no discernible effect on any of the parameters studied.

The fact that significantly more preovulatory oocytes were harvested in the control group may suggest a somewhat compromised ability in the UI group to respond to exogenous stimulation. This diminished ability for multiple recruitment was more than compensated for in the later stages of the IVF-ET procedure. The study population had a higher conception rate, higher viable pregnancy rate, and somewhat lower incidence of miscarriage. This discrepancy between the number of preovulatory oocytes and embryos, and the subsequent pregnancy rates, suggests better embryo quality and/or a more favorable endometrial milieu for embryo implantation and sustenance. The latter may not be ascribed to E_2 and P patterns throughout the cycle, since these patterns were virtually identical in the study and control populations (data not shown).

Our fertilization rates are compatible with those reported by Fishel and Edwards[11] and Mahadevan et al.,[12] who had acceptable fertilization rates (80 and 66.8%, respectively) in patients with UI. Even in those studies, fertilization rates of the control population were significantly higher (85 and 80.1%, respectively). A recent report by the second group[17] claims that fertilization rates are significantly higher in tubal controls than in UI patients. Nevertheless, conception rates are similar. Other authors[8,18] observed reduced fertilization of oocytes in

Table 2 Oocyte Quantity and Quality in 67 Cycles with UI Compared with 50 Control Cycles (mean ± SD)

	No. of preovulatory oocytes	No. of preovulatory oocytes with fertilization	No. of immature oocytes	No. of atretic oocytes	Oocytes with FZ*	Cycles with failed fertilization
Unexplained infertility (all)	2.8 ± 2.1	2.1 ± 1.8	2.3 ± 2.8	1.0 ± 1.1	0.5 ± 0.9	5:67
P value	<0.05	<0.05	NS	NS	NS	NS
Control	3.6 ± 2.0	2.9 ± 1.5	2.1 ± 1.3	1.3 ± 1.5	0.42 ± 0.8	1.50
P value	<0.05	<0.05	NS	NS	NS	NS
Unexplained infertility (strict)	2.7 ± 2.2	2.2 ± 1.7	2.5 ± 3.2	1.0 ± 1.2	0.5 ± 0.9	4:48

* Fractured zona.

Table 3 Outcome of IVF-ET in 67 Cycles of Patients with Unexplained Infertility versus 50 Control Cycles

	Fertilization rate	Conception rate		Miscarriage rate	Viable pregnancy rate
		Per cycle	Per transfer		
	%	%	%	%	%
Unexplained infertility (all)	70.3	32.4	37.3	22	29.2
Control	73.2	24	24.5	25	17.6
Unexplained infertility (strict)	67.4	29.2	35.9	12	31.6

UI patients (36% to 38%). Dor et al.[18] reported on a lower pregnancy rate (7.7%) in the UI group, compared with 17% in controls. Mahadevan et al.[12] reported comparable pregnancy rates (14%) in the UI group versus their control population (11%).

An additional novel technique recently has been suggested for the treatment of UI: gamete intrafallopian transfer (GIFT). Advocates of this technique claim superior results in the GIFT procedure compared with IVF.[19-21] Specifically, Molloy et al.[21] suggest that GIFT has the potential to double the pregnancy rates (from 13% to 27%) compared with IVF. Since a major difference between the two treatment modalities is the avoidance of in vitro gamete and embryo culture in the GIFT procedure, it is obvious that suboptimal in vitro culture conditions will adversely affect IVF success. In that respect, GIFT may be considered a quality control for the laboratory procedures.[21] It may be concluded that, in the presence of high, meticulously observed laboratory standards, IVF may be as efficient as GIFT for the alleviation of UI.

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IVF/GIFT SURVEY

RECEIVED
DEC 9 1988
Hon. Ron Wyden

CLINIC NAME: St. Luke's Roosevelt IVF-ET Program
ADDRESS: 1111, Amsterdam Avenue
New York, N.Y. 10025

CONTACT PERSON: Hussein K. Amin M.D.
PHONE NUMBER: (212) 523-3459

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? August 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based ______
   (c) University ~~based~~ Affiliated Hospital
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? ONE

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? ONE

6. How many other professionals participate in your clinic?
   (a) Physicians 4
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 1
   (d) Embryo Lab Technicians/Technologists 1
   (e) Other Lab Technicians/Technologists 1
   (f) Radiology (Ultrasound) Technicians 1
   (g) Psychologists/Counselors 1
   (h) Secretaries 1
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 14

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 1985 GIFT 1986

9. How many different patients were stimulated?
1987 IVF 24 1988 IVF 19
GIFT 1 GIFT 2

10. How many stimulation cycles were performed?
1987 IVF 36 1988 IVF 33
GIFT 1 GIFT 2

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 22 1988 20

How many embryo transfer cycles were performed?
1987 17 1988 16

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 2

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 100 % 1988 ___ 100 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 12 50 % 1988 IVF 12 63 %
GIFT ___ ___ % GIFT ___ ___ %
(b) Endometriosis:
1987 IVF 2 8 % 1988 IVF 1 5 %
GIFT ___ ___ % GIFT ___ ___ %
(c) Male infertility:
1987 IVF 3 13 % 1988 IVF — — %
GIFT ___ ___ % GIFT ___ ___ %
(d) Unexplained infertility:
1987 IVF 6 25 % 1988 IVF 6 32 %
GIFT 1 100 % GIFT 2 100 %
(e) Other (explain): Immunological Factor
1987 IVF 1 4 % 1988 IVF ___ ___ %
GIFT ___ ___ % GIFT ___ ___ %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 2 8 % 1988 IVF 3 16 %
GIFT 1 ___ % GIFT ___ ___ %
(b) 31-35:
1987 IVF 7 29 % 1988 IVF 7 37 %
GIFT ___ ___ % GIFT 1 ___ %
(c) 36-40:
1987 IVF 14 58 % 1988 IVF 6 32 %
GIFT ___ ___ % GIFT 1 ___ %

(d) 41-45:
1987 IVF 1 4 % 1988 IVF 3 16 %
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 1 1988 IVF —
GIFT — GIFT —

17. How many women delivered live infants from IVF/GIFT?
1987 IVF TWO 1988 IVF —
GIFT — GIFT —

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF TWO 1988 IVF —
GIFT — GIFT —

19. How many ectopic pregnancies resulted?
1987 IVF — 1988 IVF —
GIFT — GIFT —

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% NONE
GIFT ___ ___%

1988 IVF ___ ___% NONE
GIFT ___ ___%

21. What are the qualifications of the director of the embryo laboratory? Ph.D. Cell Biology

22. Who supervises the laboratory director? IVF Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? YES
If the answer is yes, please specify which program.
New York City Board of Health, Clinical Chemistry & Endocrinology

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Membership Pending

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians Two
    (b) Laboratory scientists (PhDs) —
    (c) Embryo laboratory technicians/technologists Two
    (d) Nurses 4
    (e) Other (explain) —

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Columbia-Presbyterian Medical Center
ADDRESS: 622 W. 168th St.
PH-16 IVF office
New York, NY 10032

CONTACT PERSON: Dr. Michael Darder, Medical Director
PHONE NUMBER: 212-305-9921

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/10/88

2. Does your clinic perform IVF/GIFT treatments? IVF currently GIFT in the past
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 5

6. How many other professionals participate in your clinic?
   - (a) Physicians 12
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 6
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 5½

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 2/83 GIFT 10/86

9. How many different patients were stimulated?
1987 IVF 35 1988 IVF 29
GIFT ____ GIFT ____

10. How many stimulation cycles were performed?
1987 IVF 65 1988 IVF 71
GIFT ____ GIFT ____

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 55 1988 54

How many embryo transfer cycles were performed?
1987 52 1988 53

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0% 1988 0 0%

14. What were the number and percentage of patients treated for:
(a) Tubal factor: 1
1987 IVF 26 74% 1988 IVF 19 65%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 0 0% 1988 IVF 1 3.4%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF 3 8.5% 1988 IVF 4 13.7%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF 4 11.4% 1988 IVF 4 13.7%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): PCO-1, Luteal phase defect -1 (1987)
1987 IVF 2 7.7% 1988 IVF 1 3.4%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 6 17.1% 1988 IVF 4 13.7%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF 15 42.7% 1988 IVF 13 44.8%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF 13 37.1% 1988 IVF 10 34.4%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF 1 3.9% 1988 IVF 2 6.8%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 16 1988 IVF 5
GIFT ____ GIFT ____

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 6 1988 IVF 5
GIFT ____ GIFT ____

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF All delivered 1988 IVF 4
GIFT ____ GIFT ____

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT ____ GIFT ____

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0% ________________
GIFT ___ ___% ________________

1988 IVF 0 0% ________________
GIFT ___ ___% ________________

21. What are the qualifications of the director of the embryo laboratory? Medical Doctor - she is the Director of the Center for Reproductive Science

22. Who supervises the laboratory director? Nobody - she is the Director of the Program

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
Blind embryo testing at Old Dominion University

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Application in progress.

27. Does the clinic train individuals in IVF or GIFT? NO (except for Fellows in Reproduct. Endocrinology) If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ________
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

We are currently expanding our IVF program and expect to perform more than 100 treatment cycles in 1989. In addition, our treatment protocol has been modified so as to increase the proportion of stimulated cycles that go on to egg retrieval and embryo transfer. We are also introducing an embryo cryopreservation program as of January 1989.

IVF/GIFT SURVEY

CLINIC NAME: IVF AUSTRALIA PROGRAM AT UNITED HOSPITAL
ADDRESS: 406 Boston Post Road
Port Chester, New York 10573

CONTACT PERSON: John J. Stangel, M.D.
PHONE NUMBER: (914) 934-7481

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? October 31, 1988

2. Does your clinic perform IVF/GIFT treatments? IVF Only
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 4

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 10

6. How many other professionals participate in your clinic?
   - (a) Physicians 11
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 11
   - (d) Embryo Lab Technicians/Technologists 5
   - (e) Other Lab Technicians/Technologists 3
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 2
   - (h) Secretaries 2
   - (i) Other (specify) 12 (Administrative Support Staff)

7. How many years has your infertility clinic been in operation? 2 3/4

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF March, 1986 GIFT ---

9. How many different patients were stimulated?
1987 IVF 521 1988 IVF 656
GIFT ___ GIFT ___

10. How many stimulation cycles were performed?
1987 IVF 805 1988 IVF 957
GIFT ___ GIFT ___

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 650 1988 807

How many embryo transfer cycles were performed?
1987 612 1988 753

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:

(a - e)
Primary
Diagnosis

(a) Tubal factor:
1987 IVF 148 28.4% 1988 IVF 306 46.6%
GIFT ___ ___% GIFT ___ ___%

(b) Endometriosis:
1987 IVF 32 6.1% 1988 IVF 67 10.2%
GIFT ___ ___% GIFT ___ ___%

(c) Male infertility:
1987 IVF 27 5.2% 1988 IVF 36 5.5%
GIFT ___ ___% GIFT ___ ___%

(d) Unexplained infertility:
1987 IVF 31 6.0% 1988 IVF 74 11.3%
GIFT ___ ___% GIFT ___ ___%

(e) Other (explain): *See Below
1987 IVF 46 8.8% 1988 IVF 135 20.6%
GIFT ___ ___% GIFT ___ ___%

(f)
Multiple
Diagnoses

(f) 1987 IVF 237 45.5% 1988 IVF 38 5.8%

15. What were the number and percentage of patients in the following age groups:

(a) <31:
1987 IVF 65 12.5% 1988 IVF 103 15.7%
GIFT ___ ___% GIFT ___ ___%

(b) 31-35:
1987 IVF 227 43.6% 1988 IVF 247 37.7%
GIFT ___ ___% GIFT ___ ___%

(c) 36-40:
1987 IVF 205 39.3% 1988 IVF 265 40.4%
GIFT ___ ___% GIFT ___ ___%

*Annovulatory
DES
Immune
Ovulatory Defect

Pelvic Adhesion
Sperm Ab's (female)
Other

(d) 41-45:
1987 IVF 24 4.6% 1988 IVF 41 6.2%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 154 1988 IVF 184
GIFT ___ GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 107 1988 IVF 20
GIFT ___ GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 120
GIFT ___ GIFT ___

19. How many ectopic pregnancies resulted?
1987 IVF 5 1988 IVF 12
GIFT ___ GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 36 33.6% 71 Singletons, 29 Sets of Twins,
GIFT ___ ___% 7 Sets of Triplets

1988 IVF 12 60% 8 Singletons, 9 Sets of Twins,
GIFT ___ ___% 3 Sets of Triplets

21. What are the qualifications of the director of the embryo laboratory? Trained for 2 years with Dr. Alan Trounson at Monash University; set up 3 successful IVF Programs; 8 years experience as embryologist at major IVF programs. (see below)

22. Who supervises the laboratory director? John J. Stangel, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
Endocrine Lab is New York State regulated, certified and inspected by the College of American Pathologists.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

21. Cont'd: Holds B.S. in Biochemistry from Monash University.

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
- **(a) Physicians** 11
- **(b) Laboratory scientists (PhDs)** 1
- **(c) Embryo laboratory technicians/technologists** 6
- **(d) Nurses** 14
- **(e) Other (explain)** Psychologist 3
  Support Staff 12

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

- IVF Australia currently has 2 Programs in the United States: 1 at United Hospital in Port Chester, New York and another at Waltham Weston Hospital & Medical Center in Boston, Massachusetts. This survey incorporates data only from the United Program.

- In compiling IVF Australia statistics for public and professional education, we are often asked to provide total numbers for the United States - for example, the number of babies born (currently 280) from all of our U.S. Programs.

  Overall statistics, of course, include cumulative data from both our Port Chester and Boston facilities, as well as from the Birmingham, Alabama Program that was affiliated with IVF Australia until July, 1988.

- 222 babies have been born through the IVF Australia Program at United Hospital; 120 couples are now expecting.

- Our "take-home-baby" rate per completed cycle is 17%.

- Our clinical pregnancy rate per completed cycle is 23%.

- IVF Australia transfers a maximum of 4 embryos per cycle, reducing the incidence of multiple births.

  Our statistics indicate that:

  - 69% of our births are singletons
  - 26% of our births are twins
  - 5% of our births are triplets

- IVF Australia incorporates Cryopreservation (embryo freezing) into its Programs.

IVF/GIFT SURVEY
Continued

- IVF Australia is a 24-hour/day, 7 day/week operation, eliminating the possibility of cycle cancellations due to missed oocyte retrievals.
- IVF Australia pioneered and uses non-surgical ultrasound-guided egg retrieval to obtain ova for fertilization.
- IVF Australia maintains a staff of psychologists to counsel couples about any aspect of treatment or their infertility problems.
- IVF Australia facilities are self-contained and include a dedicated IVF laboratory and operating room in the OR complex.
- IVF Australia maintains comprehensive, proprietary Department Operating Guidelines (for departments such as nursing and embryology), Program Operating Procedures (for our applicant services and patient services divisions, for example) that outline step-by-step implementation, and quality assurance protocols for each of our services.
- Our medical advisory board, which consists of Dr. Richard Marrs, Good Samaritan Hospital, Los Angeles, California; Dr. David Meldrum, South Bay Hospital, Redondo, California; Dr. Alan Trounson, Monash University, Melbourne, Australia; and Prof. Carl Wood, also of Monash, reviews protocols to ensure optimal patient care.
- As a provider of clinical services rather than a research-based organization, we focus on the use of proven protocols that have passed the peer review of our medical advisory board.

IVF Australia Program at United Hospital

406 Boston Post Road
Port Chester, New York 10573
(914) 934-7484

December 14, 1988

Representative Ron Wyden
Chairman
Subcommittee on Regulation
and Business Opportunities
Suite 1406
Longworth House Office Building
House of Representatives
Congress of the United States
Washington, DC 20515

Dear Representative Wyden:

As one of the nation's leading providers of in vitro fertilization -- we believe that more couples are currently cycling with our program than with any other -- IVF Australia applauds the Subcommittee on Regulation and Business Opportunities' review of infertility treatments. Your efforts to establish uniform IVF success rate reporting and performance standards, particularly for embryology laboratories, are certain to clarify options and enhance patient care.

Per your letter of 11 November, enclosed is IVF Australia's completed IVF/GIFT survey. Our "take-home-baby" rate of 17% per completed cycle, which we believe to be among the best available worldwide, has been calculated from careful analysis of our database.

In addition, IVF Australia maintains comprehensive, proprietary Department Operating Guidelines (for departments such as nursing and embryology), Program Operating Procedures (for our applicant services and patient services divisions, for example) that outline step-by-step implementation, and quality assurance protocols for each of our services.

To provide an example of the level of detail of this documentation, we have attached the table of contents from our 225-page Embryology Laboratory Departmental Operating Guidelines.

Our medical advisory board, which consists of Dr. Richard Marrs, Good Samaritan Hospital Los Angeles, California; Dr. David Meldrum, South Bay Hospital, Redondo California; Dr. Alan Trounson, Monash University, Melbourne, Australia; and Dr. Carl Wood, also of Monash, reviews these protocols to further ensure optimal patient care.

In your letter you cite three areas of primary concern, as stated in the November 1987 issue of Fertility and Sterility: inappropriate use of credentials, misuse of new technologies, and truth in advertising. Within our literature we make every effort to provide straightforward information about our professionals' affiliations, accreditation, and experience. As a provider of clinical services rather than a research-based organization, we focus on the use of proven protocols that have passed the peer review of our medical advisory board. Thus, we reduce the potential for misuse of new technologies in IVF and optimize the quality of care delivered to our patients. Finally, with regard to truth in advertising, our educational materials attest to our willingness to share information with both the public and the medical community.

Enclosed, for your information, are a sample IVF Australia patient information package, our patient newsletter (LifeTimes), and our physician-oriented Medical Report. Our public and professional education program also includes public seminars, Grand Rounds at medical centers, and two patient videotapes -- one on our consultation process and one providing medication instruction.

IVF Australia supports initiatives that will ultimately simplify difficult choices for couples with infertility problems. We certainly wish we could guarantee every couple a child, but we are proud of our achievements. Through your recommendations, we hope to be able to further improve our program.

If you have further questions about IVF Australia, please do not hesitate to call me at (203) 854-0657. I will remain at your disposal.

Sincerely,

John Stangel

John Stangel, MD
Program Medical Director

IN VITRO
FERTILIZATION
WITH
IVF AUSTRALIA

[redacted]

INTRODUCTION

Infertility is a common problem that affects both men and women in the prime of their lives. It is estimated that one out of six couples in the U.S. has difficulty conceiving.

To help solve a number of infertility problems, IVF Australia draws on the expertise of a world-renowned team of physicians and reproductive scientists from Melbourne, Australia, who are pioneers in the treatment of infertility – particularly in vitro fertilization (IVF) – and who are responsible for approximately 500 births in Australia since 1980.

In 1986, IVF Australia established programs in the U.S. to provide IVF treatment for infertile couples in this country. IVF Australia's U.S. programs have attained success rates that are among the best in the world – averaging one clinical pregnancy for every four completed IVF treatment cycles.

IVF Australia recognizes the importance of bridging an often frustrating gap between the needs of couples who are unable to have children and the sophisticated medical technology that is revolutionizing infertility treatment. To meet this need, each program includes extensive counseling and support that combines personal sensitivity and care with an extraordinary medical procedure.

In addition, our experience shows that insurance covers many of the costs associated with our treatment.

We hope this brochure will provide information to help you make an informed, realistic and appropriate decision about pursuing treatment with IVF Australia.

HISTORY OF IVF

In the late 1960s, there was an increased awareness of the extent and severity of infertility. Many couples who were unable to have children faced great uncertainty about the prospects of becoming parents, however, technological advances helped create new hope.

By the late 1960s, Professor Carl Wood in Melbourne, Australia, developed an artificial fallopian tube that was designed to replace a damaged one. In Sydney, Dr. Neil Moore suggested new ways of collecting human eggs that could be fertilized in a laboratory and, as embryos, transferred to patients.

At the same time, in England, Robert Edwards fertilized human eggs in a laboratory, achieving normal early embryonic growth, while Dr. Patrick Steptoe, also in England, began perfecting laparoscopy as a promising way to examine the ovaries and retrieve eggs.

By the early 1970s, reproductive scientists in Melbourne formed the first in vitro fertilization team, which, in 1973, attempted the laboratory fertilization of eggs and sperm following a laparoscopic egg collection. In the meantime, interest in this new field spread, and progress continued at several infertility centers in Australia, Europe and the U.S.

In 1978, Drs. Edwards and Steptoe in England, having pooled their vast experience, perfected the winning procedure. The result: the birth of the world's first IVF baby, a healthy girl named Louise Brown.

As its name implies, in vitro fertilization lets the natural process of conception and fertilization take place outside

of the body. The early embryo (four to eight cell stage) is then transferred to the wife's uterus in an attempt to establish the pregnancy.

With the promise of in vitro fertilization confirmed, the scientists and clinicians at Monash University in Melbourne, Australia, organized their team more formally. By the end of 1980, the Monash group was responsible for several in vitro births.

Refinements and enhancements to IVF technology continued quickly. Dr. Alan Trounson, a world-renowned reproductive biologist and embryologist, and colleagues at Monash University in Melbourne, were the first to successfully administer fertility drugs to stimulate the production of several eggs at one time. This provided more embryos for implantation and increased the chances for pregnancy.

The team then developed the techniques to help eggs mature, quality control systems for the fluids used to culture eggs and embryos in the laboratory, as well as improved equipment that enabled gentler egg collection and embryo transfer.

More recently, the team has developed techniques that allow for the successful freezing and thawing of embryos, the donation of eggs for women who cannot produce their own, and the collection and selection of sperm for the best chances of fertilization.

As a result of these advanced developments, the Monash team, in 1984, announced the first birth following the freezing and thawing of an embryo. This technique, known as embryo cryopreservation, gives patients the option of saving and storing embryos from one treatment cycle thus lessening the risk of a multiple pregnancy. Storing extra embryos for future attempts eliminates the need to retrieve additional eggs from the woman should the first treatment prove unsuccessful – or should another child be desired.

With these proven technological advances and a well-established IVF treatment program successfully underway, administrators and scientists began to look for ways to provide improved treatment for patients in the United States.

IVF Australia (IVFA) is the outcome of that goal – complete patient-oriented IVF programs in America based on the proven technology developed by the Monash team in Melbourne.

TREATMENT WITH IVF AUSTRALIA (IVFA)

In vitro fertilization, like traditional pregnancy, is the result of a perfectly timed series of biological events controlled by the hormones of reproduction. IVFA physicians and scientists assist only when problems in the natural process cause infertility.

In normal reproduction, the ovaries of a woman release an egg that ultimately is united with sperm from a man. This union occurs in the distal portion of the fallopian tube which extends from the uterus toward the ovary. In the IVF process, the union – fertilization – occurs in the laboratory after the egg and sperm have been collected from the wife and husband. Transferring the resulting embryo to the woman's uterus may reestablish the natural chain of reproductive events.

Before a couple begins IVFA treatment, it is important to determine clearly whether the couple's infertility can be treated with this procedure. Treatable conditions include infertility associated with tubal damage or nonfunctioning tubes, low sperm counts or low motility, resistant pelvic endometriosis, unexplained infertility and other select conditions.

The treatment includes five basic steps: (1) preliminary clinical evaluation of the wife and husband; (2) stimulation and collection of the egg(s) from the wife; (3) collection and preparation of motile sperm from the husband; (4) support and evaluation of fertilization and subsequent early embryo growth in the laboratory; and (5) transfer of the early embryo to the wife's uterus.

To control the timing of the egg release and to increase the chance of collecting more than one egg, the wife is treated with fertility medication which stimulates multiple eggs to develop. This process is monitored with ultrasound scans of the wife's ovaries and a hormonal analysis of blood samples.

With this information, clinicians can calculate the expected timing of egg release. Physicians also decide whether another injection of fertility medication will induce final maturation and prepare the eggs for release and collection.

Because fertility medication is used, more than one egg is frequently collected. Before beginning treatment, a couple will need to understand and decide on the options regarding the eggs and embryos that will not be used in the treatment cycle (see Embryo Cryopreservation for further information).

Non-Surgical Option Developed for Egg Retrieval

To retrieve mature eggs, one of several techniques is used—laparoscopic retrieval or ultrasound guided retrieval through the vagina. Laparoscopy, a surgical procedure, requires a general anesthetic. Ultrasound retrieval, on the other hand, a non surgical procedure developed more recently, requires only mild sedation and is used almost exclusively for IVFA egg retrievals.

Kathryn L. Honea, M.D., medical director of IVF Australia, is a leading expert in ultrasound guided egg retrieval which uses a thin needle, guided through the vagina, to reach the egg sac in the ovary. She was the first to use this vaginal ultrasound guided technique to obtain an IVF pregnancy in the United States.

These techniques are used to extract the eggs in their protective fluids from the follicles—structures on the ovaries that contain the eggs. The timing of this procedure is crucial. If the egg is collected too early, it may not develop properly and may fail to fertilize. If the procedure is delayed, the egg may already have been released and thus lost. Not every follicle contains an egg, and some eggs may not fertilize.

Once the fluid is collected, it is sent to the laboratory where the embryologist identifies the eggs and places them in a small dish with a culture medium. The husband is then asked to produce a specimen of semen. The semen is specially prepared so that the most active sperm cells can be selected. When the male partner is infertile, a suitable quality and number of sperm must be obtainable, either by treating the husband's sperm or obtaining specimens from a donor.

The sperm is then mixed with the egg and placed in an incubator for 48 to 72 hours to allow for fertilization and early embryo development (once fertilization has occurred, the egg becomes an embryo). Embryologists examine the culture at regular intervals to make sure that fertilization and embryo development are taking place normally. If the embryo is developing properly, it is then transferred to the wife's uterus—usually the second day after the eggs and sperm have been collected.

Transferring the embryo to the woman's uterus is a nonsurgical procedure, and is usually completed in 10-15 minutes. A very thin tube carrying the embryo is gently introduced through the cervix into the uterus. Since this procedure is usually painless, no anesthetic is needed. The woman, however, is asked to rest for a few hours before returning home.

About two weeks after the embryo transfer, further blood samples are taken and analyzed. Based on laboratory tests of these samples, the physician and laboratory scientists can determine whether or not the transferred embryo or embryos have implanted in the uterus and whether embryo development is proceeding.

Further ultrasound monitoring four to five weeks after the embryo is transferred may reveal the developing embryo. Soon after that, it may be possible to detect fetal heart activity, a clear sign of successful implantation.

Embryo Cryopreservation

The embryo cryopreservation technique was developed in part to help solve the medical and ethical problems associated with embryos that are formed but not used during an IVF treatment cycle.

IVFA's current pregnancy success rates have been obtained by transferring no more than four embryos to the uterus of an IVF patient. Transferring more than four embryos in one IVF cycle can increase the risk of multiple births to a medically unacceptable level. In some instances during egg retrieval, no eggs may be obtained, in other cases, nine or ten eggs may be obtained. Therefore, more eggs may be retrieved than will be used in a single IVF cycle, and more than four embryos may result after fertilization.

An obvious benefit of embryo cryopreservation is the chance of achieving pregnancy with cryopreserved embryos during a later cycle without the cost and inconvenience of additional egg-retrieval. Frozen embryos will be stored for up to five years. If, during that time, the couple wants to use the stored embryos, some or all of them can be thawed and examined to determine whether they are suitable for transfer to the uterus.

Couples wishing to have their excess embryos frozen will be required to make certain decisions before the IVF egg stimulation cycle begins. Decisions

that must be made include: How many eggs may be fertilized in one treatment? How many embryos may be transferred?; and What is to be done with any excess embryos?

The technically advanced procedures developed at Monash University and used at IVF Australia programs in the U.S. give couples more choices than they might have elsewhere. As a result, couples must make an informed and thoughtful decision on these matters and should discuss them thoroughly with IVFA physicians and counselors.

Patient Care and Counseling

In addition to applying the latest proven medical techniques, IVF Australia has established a comprehensive program of individual patient care and counseling, developed by Patricia Honea-Fleming, Ph.D, chief psychologist for IVFA. Dr. Honea-Fleming has studied coping strategies and treated infertility patients for many years.

Such personal attention begins with the medical staff's careful evaluation of each couple's medical records prior to consultation. At the time of consultation, both husband and wife attend informational and counseling sessions with the physician, nurse coordinator, psychologist, and financial counselor.

The nature of their infertility problem is explored and treatment options, procedures and the prospects for success are thoroughly discussed.

A variety of support techniques, including individual counseling and group sessions, are arranged by the program psychologist to help meet the needs of couples during the treatment cycle. The staff also maintains close communication with the referring physician, if so desired by the couple.

[redacted]

SUMMARY

IVF Australia Programs provide comprehensive infertility treatment with a ensitivity to the individual medical *and* emotional needs of infertile couples eking care.

Because IVF is a demanding procedure, it should be considered only if professional evaluation determines that there is a reasonable probability of success, and only after other treatment options have been considered. We urge couples contemplating IVF treatment to discuss these options first with their obstetrician-gynecologist or infertility specialist and with their local infertility patient-support group. Couples may then wish to submit medical records leading to a consultation and treatment.

For those couples who may benefit from in vitro fertilization, IVF Australia Programs offer a proven, world-renowned treatment, a wealth of medical and scientific experience, and a sensitive and dynamic approach incorporated in a procedure of complete patient care.

If you would like to know more about IVF Australia Programs, please contact us. More information may be obtained by calling (203) 854-5501 or writing to IVF Australia (U.S.A) Ltd., P.O. Box 15, Rowayton, CT 06853.

IVF AUSTRALIA PROGRAM AT UNITED HOSPITAL

406 Boston Post Road
Port Chester, NY 10573
(914) 934-7484

APPLICATION/ACCEPTANCE PROCEDURE

Your application to seek treatment with the IVF Australia Program at United Hospital will be processed with appropriate urgency and attention to detail. Together we will need to determine whether:

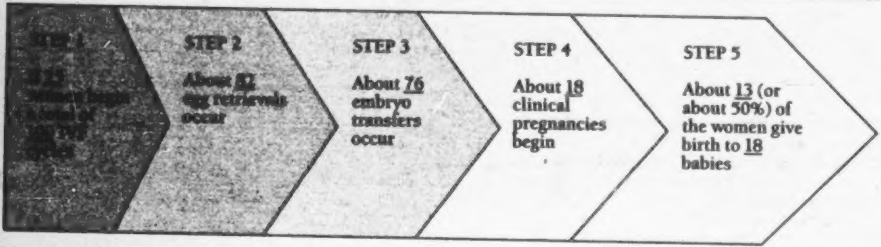
- in vitro fertilization is advisable for you;
- you can enter treatment in a time frame convenient for you;
- you are comfortable with signing our informed consent form.

The following outline will help you estimate the time requirements and probability that your condition makes you acceptable for treatment.

STEPS	ESTIMATED TIME REQUIRED
1. You return enclosed application.	**3 days**
2. We receive and review your medical records.	**2 to 4 weeks**
3. Our medical staff discusses with you whether additional tests are indicated and how they should be conducted. (If you have been treated for infertility for more than a year, it is likely that your existing medical records are adequate .)	**Within 2 weeks of receipt of existing medical records.**
4. An initial consultation is arranged and you receive our second information packet which contains more detailed information and consent forms. At the consultation, you will meet as *a couple* with a physician, nurse, psychologist and financial counselor.	**Within 2 to 4 weeks of receipt of complete medical records.**
5. If treatment is advised, your first treatment cycle is scheduled.	**Treatment to begin within 2 months after you are accepted for treatment, providing that a space is available within the Program's schedule.**

LIKELY TREATMENT OUTCOMES

The most meaningful way to express IVF success rates is the chance of treatment resulting in a *live birth*. Our experience indicates that if any patient at an IVF Australia Program completes four IVF treatment cycles, the chance of giving birth is expected to be about 50%. Some women establish a successful pregnancy after one attempt, others after several tries, and some do not become pregnant after repeated attempts, depending on the woman's age, the number of embryos available for transfer and to some extent, cause of infertility. Please review the diagram below to understand how success is likely to evolve from each important step in a treatment cycle.



STEP 1

25 women begin a total of [illegible] IVF cycles

STEP 2

About 82 egg retrievals occur

STEP 3

About 76 embryo transfers occur

STEP 4

About 18 clinical pregnancies begin

STEP 5

About 13 (or about 50%) of the women give birth to 18 babies

Please note that embryos frozen in an IVF treatment cycle and transferred during a subsequent menstrual cycle may result in additional live births.

COST OF TREATMENT

While your treatment may vary depending on your individual needs, you can determine approximate costs from the following sample breakdown of costs that could be incurred during treatment. Please note that this is our current estimate of costs and may change. Costs have been grouped as:

- Basic Evaluation (the basic testing and consultation required prior to your first IVF treatment cycle);
- An IVF Treatment Cycle;
- Cryopreserved Embryo Cycle (applies when you are having embryos transferred which were frozen during one or more prior IVF treatment cycles).

We will assist you in both evaluating and obtaining insurance coverage for treatment. However, we ask that you plan to deposit with us the full cost of treatment in advance.

The following reflects a sample breakdown of fees that could be incurred during an IVF treatment cycle up to and including the first pregnancy test.

SERVICES	BASIC EVALUATION (1st cycle only)	IVF TREATMENT CYCLE Nonsurgical (payable in advance of cycle)	CRYOPRESERVED EMBRYO CYCLE
Initial Consultation	**200**		
Comprehensive Physical & Medication Instruction	**125**		
Hormone Assays (if necessary)	**(281)**		
Endocrine Monitoring		**1,295**	**1,425**
Ultrasound Monitoring		**220**	
Egg Retrieval—Physician's Services		**1,000**	
Embryology		**715**	**640**
Embryo Transfer—Sounding of Uterus		**100**	**100**
Ambulatory Surgery		**1,700**	**675**
Anesthesiologist		**300**	

NOTE:

1. If the option of cryopreservation is chosen, a $400 embryology fee will be charged at the onset of each treatment cycle in which embryos are collected and frozen. This fee is credited to the amount charged for a cryopreservation cycle.

2. A $300 nonrefundable administrative fee is required at the onset of each cycle.

3. If your treatment is discontinued in mid-cycle, your charges will reflect services incurred up to the point of cancellation.

4. Occasionally a surgical retrieval is medically necessary and an additional $700 charge is incurred.

5. In our experience, most patients have obtained partial insurance coverage of our fees.

6. Above fees do not include cost of medication and self-administration teaching, estimated to be $580 per cycle.

7. Fees are subject to change.

YOUR TIME REQUIREMENTS

IVF Treatment Cycle

An IVF treatment cycle requires patient participation during the first half of your menstrual cycle. The specific nature of the participation will be tailored to your history and response as treatment progresses but can be generalized as shown below.

Please keep these variables in mind in determining how much of your time a treatment cycle requires.

- the distance between your home and United Hospital (see TRAVEL/ ACCOMMODATIONS).
- daily injections and additional blood samples can be arranged at home or near your home.
- your personal needs and preferences for counseling during treatment.

APPROXIMATE DAY OF YOUR MENSTRUAL CYCLE	YOUR TIME REQUIRED (Excluding travel time)	NATURE OF YOUR PARTICIPATION
Day 1	**10 minutes**	**• Telephone the Program and confirm you are beginning a treatment cycle.**
Daily from day 1, 2, 3, or 4 to day 13	**30-90 minutes daily**	**• Receive hormone stimulation by pill and/or injection. • At the Program or near home (if arrangements can be made) have a blood sample drawn and have an ultrasound exam as needed. • On days 9-13 you may be asked to provide additional blood samples. • Prior to egg retrieval complete hospital pre-admission testing.**
Day 15	**3-4 hours**	**• Undergo nonsurgical ultrasound guided egg retrieval (does not require general anesthesia or associated recovery period).**
Day 17	**2-3 hours**	**• Return to Program for transfer of successfully fertilized egg(s) to uterus. You may choose to have additional potentially viable embryo(s) frozen.**
Days 28-30	**15 minutes**	**• Have blood drawn for pregnancy test.**

YOUR TIME REQUIREMENTS

Frozen Embryo Transfer Cycle

If you have had embryos from a treatment cycle frozen (cryopreservation) and stored, they can be transferred to the uterus during a subsequent menstrual cycle. Frozen embryo transfer cycles are much simpler (and also less costly) than an IVF treatment cycle in which eggs are collected. In our experience, 15% of patients who have retrievals have embryo(s) which can be frozen after each treatment cycle.

APPROXIMATE DAY OF YOUR MENSTRUAL CYCLE	YOUR TIME REQUIRED (Excluding travel time)	NATURE OF YOUR PARTICIPATION
Day 1	**10 minutes**	**• Telephone the Program to confirm you are beginning a frozen embryo transfer cycle.**
Daily from day 8 to 14	**30 minutes daily**	**• Have a blood sample drawn twice daily.**
Day 18	**2-3 hours**	**• Have frozen embryo(s) transferred to the uterus.**
Days 28-30	**15 minutes**	**• Have blood drawn for pregnancy test.**

TRAVEL/ACCOMMODATIONS

United Hospital is located in Port Chester, New York, in Westchester County—at the intersection of I-287 and I-95—about 15 miles northeast of New York City.

BY AUTOMOBILE

- From New York City – East Side:
Take I-95 North to Exit 21 (Route 1 North, Port Chester). At the end of the ramp, proceed onto Route 1. At the first light, turn left into the hospital parking lot.

- From New York City – West Side:
Take the West Side Highway to the Henry Hudson Parkway to the Saw Mill River Parkway. Take first exit after toll to Cross Country Parkway East to Hutchinson River Parkway North to 287 East (Rye). Take Exit 12, bear right on ramp. At first traffic light, turn left and then right into the hospital parking lot.

- From upper Westchester, or Rockland:
From upper Westchester, take I-684 to I-287 East. From Rockland, take the Tappan Zee Bridge to I-287 East. Get off at Exit 12 (Route 1, Port Chester) and bear right, circling back over I-287. At the first light, turn left into the hospital parking lot.

- From Connecticut:
Travel south on I-95, take the exit for I-287 West and immediately follow the sign for Exit 21 (Midland Avenue, Port Chester). Turn left at the end of the ramp, then take the first right. At the next light, turn right onto Route 1 North. In about a ½ mile, turn left into the hospital parking lot.

BY TRAIN

- Take the New Haven line from Grand Central Station in Manhattan to Rye, New York (approximately a ½ hour trip). Cabs are available to the hospital, which is ¼ mile from the Rye station. (There is a station in Port Chester, but Rye is closer.)

BY PLANE

- United Hospital is located about 15 miles from LaGuardia Airport in New York City, and three miles from Westchester County Airport in White Plains, New York. The Rye Town Hilton, which is 1 mile from the hospital, offers limousine service from LaGuardia to the hotel.

We can provide additional information on area accommodations.

IVF Australia Program at United Hospital

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THE FACILITY AND THE STAFF

IVF AUSTRALIA PROGRAM AT UNITED HOSPITAL

406 Boston Post Road
Port Chester, NY 10573
(914) 934-7484

The IVF Australia Program at United Hospital is the first of its kind to be established in the United States. It is the result of a partnership between IVF Australia and the internationally recognized team of scientists and clinicians from the highly successful IVF program at Monash University in Melbourne. The Monash team, headed by Dr. Alan Trounson, is responsible for many of the important advances in IVF technology and is credited with several hundred births.

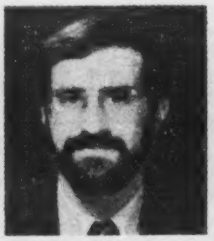
The program at United Hospital combines the expertise of Australian and American physicians, scientists, clinicians, nurses, psychologists and administrators using the proven technology developed and successfully employed since 1980 at Monash University in Melbourne, Australia.

The IVF Australia Program at United Hospital operates in a separate area of the hospital which is dedicated to the treatment of infertility through IVF services.

United Hospital is a 306-bed, acute-care, nonprofit hospital located in Port Chester, New York, about 15 miles northeast of New York City in Westchester County. Fully accredited by national and state hospital associations, United has a 250-member medical and dental staff. It also has established several advanced family-centered maternal care units and services, including specialized birthing rooms and expectant parent classes.

THE STAFF

John Stangel, M.D.



Joel Novendstern, M.D.

Albert Parker, M.D.

Ronald J. Reiss, M.D.

Program Medical Director

John Stangel, M.D., is a board certified reproductive endocrinologist with experience in the treatment of infertility. In addition to his responsibilities as medical director of the IVF Australia Program at United Hospital, Dr. Stangel has been in private practice for 12 years, specializing in reproductive endocrinology and infertility. He has also been a clinical associate professor in the Department of Obstetrics/Gynecology at New York Medical College, and the director, Section of Reproductive Endocrinology and Infertility, at New York Medical College, Metropolitan Hospital in New York and Westchester County Medical Center.

Upon graduating from New York Medical College, Dr. Stangel completed his internship at Beth Israel Medical Center in New York, his residency in obstetrics and gynecology at Mount Sinai Hospital in New York, and a fellowship in reproductive endocrinology and infertility at New York Medical College. The president and co-founder of the Tri-State Reproductive Endocrinology Society, Dr. Stangel has been a fellow of the American College of Obstetrics & Gynecology (ACOG), a board member of the American Association of Gynecological Laparoscopists (AAGL) and a member of the American Fertility Society (AFS) He has also written extensively on the subject of infertility for a variety of medical publications and books. Dr. Stangel also maintains a private infertility practice in Rye, New York.

Senior IVF Clinicians – specially trained to conduct consultations and to perform egg retrieval and embryo transfer procedures.

Joel Novendstern, M.D., has been in private practice in Mt. Kisco, New York, for 9 years, specializing in obstetrics, gynecology and infertility, in addition to his role as a senior IVF clinician for IVF Australia. Dr. Novendstern is a graduate of the Georgetown University School of Medicine, having served his residency in obstetrics and gynecology at New York Medical College. He is a fellow of the ACOG and a member of the AFS as well as a contributing author to a textbook on infertility surgery.

Albert Parker, M.D., associated with United Hospital for 24 years, has been chairman of its Department of Obstetrics-Gynecology. He also has been in private practice in Rye, New York, for 24 years, specializing in obstetrics and gynecology. Dr. Parker is a graduate of Harvard Medical School, having served his residency in obstetrics and gynecology at Boston City Hospital. He is a member of the ACOG, AAGL and the Westchester County Medical Society, among others.

Ronald J. Reiss, M.D., has been in private practice in Manhattan for 8 years, specializing in obstetrics, gynecology and infertility, in addition to his role as senior clinician for IVF Australia. Dr. Reiss is a graduate of the University of Brussels, Belgium Faculty of Medicine,

Pedro R. Rojas, M.D.

Michael Wenof, M.D.

Ellen Jacobs, PhD.

Sandra Schoeneman, PhD.

having served his residency in obstetrics and gynecology at Woman's Hospital division of St. Luke's-Roosevelt Hospital Center. A member of the attending staffs at Lenox Hill Hospital and St. Luke's-Roosevelt Hospital Center in New York City, he is a fellow of the ACOG and a member of AFS.

Pedro R. Rojas, M.D., associated with United Hospital for 12 years, is vice chairman of its Department of Obstetrics and Gynecology. He has also been in private practice for 12 years, specializing in obstetrics and gynecology. Dr. Rojas is a graduate of San Marcos University in Lima, Peru, having served his residency in obstetrics and gynecology at Albert Einstein College of Medicine. He is a member of the ACOG, AAGL, American Medical Association and the World Medical Association.

Michael Wenof, M.D., is a director emeritus, Service of Reproductive Endocrinology and Infertility at the Nassau County Medical Center, State University of New York. He has been in private practice in Levittown, New York, for 12 years, specializing in reproductive endocrinology and infertility. A graduate of Jefferson Medical College in Philadelphia, Dr. Wenof was a resident in obstetrics and gynecology at Temple University Hospital, with additional training in reproductive endocrinology and gynecological laser and reconstructive microsurgery. A member of the ACOG, Dr. Wenof has published extensively in his field.

Program Psychologists – provide patient care and counseling services.

Ellen Jacobs, PhD., specializes in the treatment of the emotional response to the medical problems and illness. In addition to her work as an IVF program psychologist, she has been in private practice for 7 years in New York City.

Dr. Jacobs received her doctorate in psychology from the University of Tennessee. She completed an internship at the Nassau County Medical Center and a fellowship at Memorial Sloan-Kettering Cancer Center in New York City. Currently, she is doing post-doctoral work in psychoanalysis at New York University. Dr. Jacobs is the author of articles on the psychological response to certain kinds of surgery.

Sandra Schoeneman, PhD., specializes in the treatment of the emotional aspects of infertility as well as the treatment of post traumatic stress disorders. In addition to her work at IVF Australia, she has been in private practice for 6 years in Westchester County.

Dr. Schoeneman received her doctorate in clinical psychology from Fordham University. She completed an internship at the Bronx Veterans Administrative Medical Center and worked for several years for the Veterans Administration.

Currently, she is doing post-doctoral work in psychoanalysis at the Westchester Center for the Study of Psychoanalysis and Psychotherapy.

IVF Clinical Team – private practitioners, specially trained by IVF Australia, may perform egg retrieval and embryo transfer procedures.

Nurse Coordinators – are in daily contact with patients during each step of treatment.

Joan Walker-Johnson, R.N., B.S.N., M.A., Lehman College, Columbia University Manager of Nursing Services
Rena Berger, R.N., B.A., B.S.N., University of Wisconsin, Boston University
Judith Gallo, B.A., R.N., F.N.P., M.S.N., Pace University
Roberta Jones, R.N., B.S., Iona University
Mary Anne LaRosa, R.N., B.S.N., Russell Sage College
Eileen Madsen, R.N., B.S.N., Lehman College
Cathy Martyn, B.A., F.N.P., M.S.N., LeMoyne University, Pace University
Joanne Shaw, R.N., B.S.N., M.S.N., City University, New York University
Sharon Sousa, R.N., B.S.N., University of Connecticut

Nursing Assistants, **Pat Jamieson, Audrey Loveridge**, **Ida Mendes**

Embryology Technicians – combine egg and sperm in the laboratory following retrieval and perform embryo cryopreservation techniques.

Manager of Lab Services, **Donna Howlett, B.S.**, Monash University, Australia
Katrine Chiou, B.S., Pace University
Ermine Ciaston, B.S., University of Scranton
Carol-Ann Cook, B.S., M.S., Long Island University
Kathleen Crumm, M.T., Phoenix College
Timothy Schimmel, B.S., University of Delaware
Cynthia Wickersham, B.S., University of New Hampshire

RIA Laboratory Technicians – measure endocrine levels in blood samples.

Susanne Jacobs, B.S., Lafayette College
Mary Beth Palatucci, B.A., A.A.S., Mercy College, Western Comm. College
Colleen Walsh, B.S., State University College at Oneonta

Administrative Staff – ensures management and support services are provided for the entire program.

Vicki Baldwin, Executive Director
Leigh Beckley, Manager of Administration
Marlene D'Agostino, Supervisor, Financial Services
Kathleen Young-Jakes, Financial Coordinator
Alice Saltalamachia, Financial Coordinator
Dayna Kaye, Sr. Administrative Assistant
Marcelle DiBiasi, Administrative Assistant
Lisha Daigle, Administrative Assistant
Linda Duffy, Patient Coordinator
Lissen Simonsen, Patient Coordinator
Eileen Furlong, Receptionist

IVF Australia Medical Report

Volume I, Issue I January, 1988
Editor: Kathryn L. Honea, M.D., Corporate Medical Director

In response to physician inquiries, IVF Australia begins a regular series of medical reports to provide a continual update on:

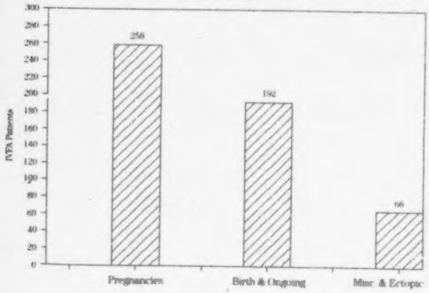
- application of assisted reproductive technology in therapy of infertile couples;
- results of therapy at IVF Australia Programs;
- progress in therapeutic modalities.

The first issue of the Medical Report will focus on in vitro fertilization (IVF). Defined as fertilization "in glass," IVF allows the process of fertilization to occur in the laboratory after removal of eggs from the woman's ovary(s) and insemination with her husband's sperm. Approximately 48 hours later, after normal fertilization occurs, the embryo is transferred to the woman's uterus in the attempt to establish a pregnancy.

IVF Australia Programs provide exclusively *non-surgical* egg retrieval and now have one of the most extensive worldwide experience bases. Laboratory technology at IVF Australia is founded on techniques and procedures developed by the IVF team led by Professor Carl Wood and Dr. Alan Trounson.

Success in therapy is helping a couple obtain a *clinical* pregnancy which results in a live born. At IVF Australia Programs a clinical pregnancy is defined as a gestational sac on ultrasound or the products of conception on D&C, or an ectopic pregnancy. The two programs have assisted 685 couples who have completed at least one IVF cycle to obtain 258 clinical pregnancies. 75% of clinical pregnancies should result in a live birth. As of December 31, 1987, *125 babies* have resulted from *92 births.*

IVF Australia: Clinical Pregnancy Results
(as of Nov. 30, 1987)



Overall results from IVF programs must reflect total patient involvement. All programs have a cancellation rate during ovulation induction (IVF Australia rate is 18%). At IVF Australia Programs in less than two years:

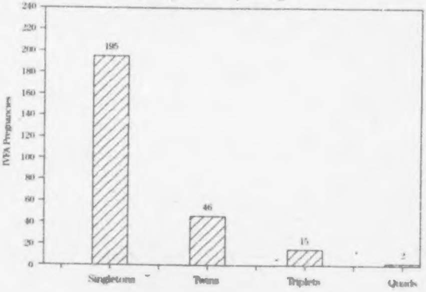
IVF Australia: Table 1 (as of Nov. 30, 1987)

685 couples have:

completed	1187	retrievals
received	1081	transfers
obtained	258	clinical pregnancies
which should result in	**192**	births
of an estimated	**285**	babies

Multiple pregnancies have inherent risks for the mothers and resulting babies. By limiting the total number of embryos per transfer to four, multiple gestations greater than twins have been kept to 6.6% of all clinical pregnancies occuring at IVF Australia Programs.

IVF Australia:
Multiple Gestations In Clinical Pregnancies
(as of Nov. 30, 1987)



Affect of Number of Embryos Transferred on Pregnancy Outcome

Clinical pregnancy rates appear to be strongly associated with the total number of embryos transferred. The best clinical pregnancy rates, 31% per transfer, occur in patients receiving 4 embryos during each transfer (4ET).

IVF Australia: Table 2 (as of Nov. 30, 1987)

No. of Embryos	No. of Patients	No. of Transfers	No. of Pregnancies	Pregnancy/ Transfer	Pregnancies/ Patient
4	301	511	157	157/511 31%	157/301 (52%)
3	219	313	67	67/313 21%	67/219 (31%)
2	101	158	23	23/158 15%	23/101 (23%)
1	64	99	11	11/99 11%	11/64 (17%)
Total	685	1081	258	258/1081 24%	258/685 (38%)

259 couples have completed *more than one cycle* at the IVF Australia Programs. Clinical pregnancy rates per transfer appear to be consistent across multiple cycles based on the number of embryos transferred.

Quality Control for IVF Programs

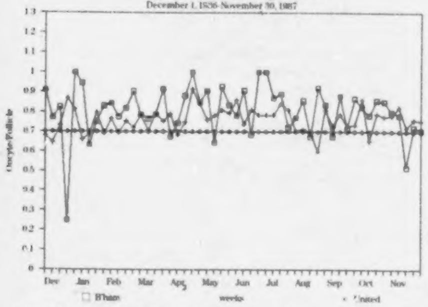
The ultimate assessment of program performance is the births resulting from the care provided. This requires years of operation and does not allow an ongoing control of performance parameters. At IVF Australia Programs, 125 babies have been born from 92 births in less than two years of operation.

Parameters which *can* be monitored include:

- egg retrieval rates (eggs/follicles aspirated) (which can be monitored per operator and collectively);

IVF Australia: Oocyte/Follicle By Week

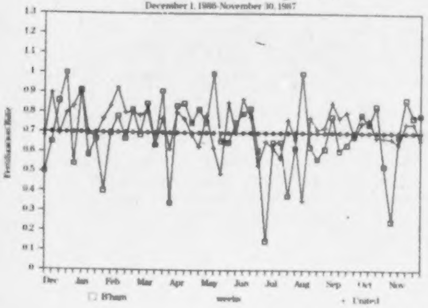
December 1, 1986-November 30, 1987



- fertilization rates (eggs fertilized per insemination);

IVF Australia: Fertilization Rate By Week

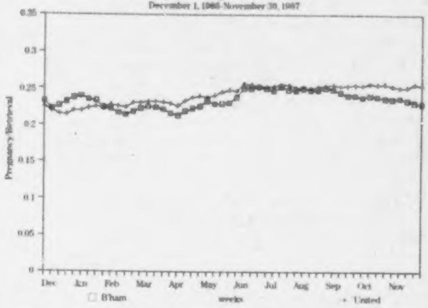
December 1, 1986-November 30, 1987



- pregnancy rate per retrieval;

IVF Australia: Pregnancy/Retrieval

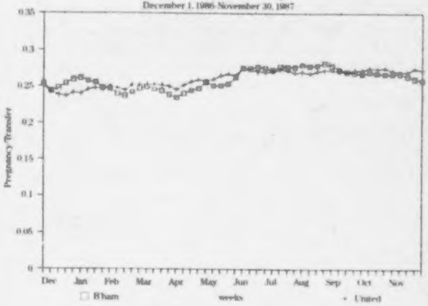
December 1, 1986-November 30, 1987



- pregnancy rate per transfer.

IVF Australia: Pregnancy/Transfer

December 1, 1986-November 30, 1987



Fertilization rates should average 70%, however, this will reflect the severity of male factor infertility in patients accepted into the program.

Indications for Therapy by In Vitro Fertilization

Standard indications include:

A. Tubal disease
  1. Failed tubal repair
  2. Fibrosis or scarring that is too extensive to be repaired
  3. Absence of tubes

B. Endometriosis
  1. With extensive scarring
  2. With or without scarring but with failure to achieve a pregnancy in one to two years following adequate surgical and/or medical therapy

  Note: Patient should not be receiving Danazol therapy for three months prior to an IVF cycle.

C. Recurrent ectopic pregnancy
  1. Patient who has had three consecutive ectopic pregnancies

D. Idiopathic infertility
  1. Two years of infertility with normal studies for:
     a) endometrial dating on endometrial biopsy
     b) hysterosalpingogram
     c) laparoscopy
     d) semen analysis
     e) post-coital test
     f) antisperm antibodies
     g) sperm penetration assay

E. Male infertility

  Normal semen parameters:
    motility>40%
    concentration>20 mil/ml
    abnormal morphology<60%

  Infertility parameters:
  1. single factor = one abnormality
  2. dual factor = two abnormalities
  3. triple factor = three abnormalities
  4. Sperm penetration assay: sub-normal results depending on performing laboratory.
  5. Antisperm antibodies: significant levels as assayed by the performing laboratory.

  Note: For 1, 4 and 5, there should be greater than two years of infertility with failed conventional therapy.

Patient Criteria

1. Couples must be married.
2. Age of the female should be less than 41 at the time of cycle (exceptions may be made for ovulatory patients with normal FSH).
3. No contraindications for ovulation induction, pregnancy or delivery, anesthesia.

Evaluation of the Infertile Couple

Prior to referral, the evaluation of the infertile couple should include:

A. Semen analysis
  1. If normal, lab study can be within the last 12 months.
  2. If abnormal, lab study must be within the last 6 months.
  3. If semen analysis is abnormal, please contact the IVF Australia Program office to determine if the count is acceptable for treatment.

B. Evidence of ovulation
  1. Mid-luteal progesterone
  2. Mid-luteal or late luteal endometrial biopsy for endometrial dating.
  3. Note that anovulatory patients are treatable.

C. Evaluation of uterine cavity
  1. Hysterosalpingogram (HSG) required to document a normal uterine cavity if;
     a) never performed,
     b) uterine surgery has been performed after a previous HSG,
     c) an abnormal uterus is noted in exam.
  2. HSG is not indicated if a normal hysteroscopy or normal full term birth has occurred in the past two to three years.

D. Antisperm antibodies and sperm penetration assay.
  1. Needed for evaluation of unexplained infertility.

E. Completion of an adequate infertility evaluation with appropriate therapy for problem found.

Medical Risk Update

IVF and congenital malformation: The Australia and New Zealand registry for IVF births has reviewed 1,694 live births and still births greater than 20 weeks' gestation and three terminations of pregnancy due to fetal abnormalities. In the 1979-1986 analysis period, there was an increase over the expected number of occurences in the general population of *two* congenital anomalies: spina bifida (6 vs. 1.2 expected) and congenital transposition of the great vessels (4 vs. 0.6 expected). This may reflect a sampling bias and will require further evaluation. The *overall congenital anomaly rate of 2.2% was not higher than the general population.* As spina bifida *may* be detected in prenatal studies, it is recommended that this evaluation be performed in all IVF pregnancies. Lancaster, *The Lancet,* Vol. II, 12/12/87, pg. 1292.

IVF Registry Data

Should you provide prenatal care for a patient with an IVF Australia pregnancy, please complete the follow-up evaluation which will be provided to you with the referral letter to collect data for the Society of Assisted Reproductive Technology IVF Registry sponsored by the American Fertility Society.

For further information contact:

Kathryn L. Honea, M.D.
Corporate Medical Director
IVF Australia Program at Birmingham
2006 Brookwood Medical Center Drive
Birmingham, AL 35209
(205) 870-0498

John J. Stangel, M.D.
Program Medical Director
IVF Australia Program at United Hospital
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Rowayton, CT 06853

Second Printing

IVF Australia LifeTimes

Volume 1, Issue 5

Six IVF Australia couples and their babies join Executive Director Beverly Freeman and Medical Director Patricia M. McShane, M.D., (top center, L-R), in celebrating the start-up of IVF Australia's Boston program.

IVF Australia Expands to Boston

IVF Australia Programs are considered among the most successful in vitro fertilization programs in the U.S. At IVF Australia's new facility at WalthamWeston Hospital & Medical Center, the IVF Australia Program—Boston uses the same proven technology developed at Monash University in Melbourne, Australia and employed successfully in the Port Chester, New York program since 1986.

The IVF Australia Program—Boston operates in a separate area of WalthamWeston Hospital that is dedicated to the treatment of infertility through IVF services. The Boston Program is directed and staffed by reproductive endocrinologists, embryologists, and psychologists from the Boston medical community.

The Boston program's medical director, Patricia M. McShane, M.D., was most recently director of the In Vitro Fertilization Program at Brigham and Women's Hospital. "IVF Australia's use of nonsurgical ultrasound-guided retrieval and the individualized care given each patient have produced remarkable results," McShane said. "So far, more than one out of four women completing one cycle has become pregnant. Infertile couples in the Boston area now have the option of the IVF Australia program, credited with the births of more than 257 babies in the U.S. since its introduction two years ago."

Beverly Freeman joins the IVF Australia Program—Boston as executive director. Freeman is known from her previous position as executive director of RESOLVE®, a nationally recognized support group for infertile couples. Her experience in helping couples cope with infertility gives her a unique perspective on people's expectations regarding an IVF program.

"IVF Australia cares about infertile couples and, therefore, has developed a program in Boston which attends to all of the couples' needs, both medical and emotional," said Freeman.

Program staff received extensive training at IVF Australia's Port Chester program to ensure patients receive the best care available. Staff is also equipped to help patients with their insurance needs.

Individuals who would like more information about IVF or IVF Australia, can write to: Patient Coordinator, IVF Australia Program—Boston, WalthamWeston Hospital & Medical Center, Hope Avenue, Waltham, MA 02254. Those who wish, may call toll-free 1-800-288-4832 from all areas including the local Boston area.

Boston-Area Couple Treated at Port Chester Program

Lori and Hugh Macnaughton of Concord, Mass., are the first Boston-area couple to become parents after treatment at the IVF Australia Program at United Hospital, Port Chester, New York.

The Macnaughton triplets, Brandon Wells, Heather Sue, and Jillian Marie, were born last spring.

Lori, age 30, and Hugh, 45, had tried for over four years to conceive before considering in vitro fertilization. Prior to IVF treatment, Lori had undergone three major and eight minor surgeries to remove the excessive scar tissue which was preventing her from becoming pregnant. When surgery and other standard infertility treatments failed, Lori's physician, Dr. John Stangel, suggested they consider IVF.

Lori and Hugh first tried IVF in 1985 at a Pennsylvania IVF program, which resulted in the birth of their now two-year-old son, Andrew. When deciding to try IVF a second time in 1987, the couple chose to rejoin Dr. Stangel, now medical director at the IVF Australia Program at United Hospital in Port Chester, New York. The Macnaughtons felt Dr. Stangel's expertise was worth the effort of travelling between their home in Concord, Mass., and Port Chester.

"We both missed the care we had gotten with Dr. Stangel, so when we heard he was involved with the IVF Australia Program, we followed him there," said Lori.

After the first cycle, Lori learned she was pregnant.

"We were convinced IVF would work for us eventually as it had with Andrew," recalls Lori, "but we just didn't think it would happen on the first try."

When asked about her pregnancy, Lori said, "It was really very easy—and, believe it or not, as babies they're still pretty easy. I guess they're just good kids!"

With the opening of the new IVF Australia Program at the Waltham-Weston Medical Center, Boston-area couples now have the opportunity for more convenient treatment.

Congressional Report Addresses Issues Related to Infertility

The Office of Technology Assessment, an arm of the U.S. Congress, recently released a study entitled *Infertility: Medical and Social Choices*. The study investigates the scientific, legal, economic and ethical issues surrounding infertility, which affects 2.4 million American couples.

In its discussion, the report raises many issues couples should be aware of when considering IVF treatment. For example, the report notes that IVF programs measure success rates in different ways. One method is to total the number of babies born. Another way of measuring is by number of pregnancies achieved, but, as the report reveals, definitions of pregnancy vary. For example, a pregnancy can be defined as preclinical, clinical, chemical, viable or a live birth.

Furthermore, the report states that some IVF programs report pregnancy rates per patient, treatment cycle, retrieval or embryo transfer. In order to make an informed decision, a couple must understand the criteria each IVF program uses to measure and report its success.

The report also states that while IVF is being practiced with more frequency, proficiency among medical teams varies widely. While 70 to 80 programs in the United States have established a record of "some" success with IVF, nearly half of the 170 total have yet to achieve a live birth as a result of IVF treatment.

Patricia M. McShane, M.D., medical director of the IVF Australia Program—Boston, recently commented on the impact of this report. "The results of the congressional report suggest that it is the implicit duty of all IVF programs to clearly outline the statistics, risks, emotional considerations, and costs to each couple considering treatment," said McShane. "However, because no uniform standards have been established for reporting statistics or rating performance among IVF programs, couples need to closely examine all the information, questioning whatever is unclear or incomplete."

As of August 31, 1988, 257 babies have been born and an additional 128 couples are expecting babies as a result of in vitro fertilization treatments since IVF Australia Programs became operational in 1986. The clinical pregnancy rate per completed treatment cycle at the programs — through embryo transfer — is approximately 23%. The birthrate per completed cycle is approximately 17%.

"IVF success rates in general," said McShane, "may be put into perspective by noting that the chances of pregnancy and birth in any woman are strongly correlated with age, and that the average IVF patient is significantly older than the average woman trying to have a child."

To receive a copy of *Infertility: Medical and Social Choices*, write to Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 or call (202) 783-3238.

Questions and Answers About IVF

In each issue of *LifeTimes*, IVF Australia presents questions frequently asked about IVF in general and the IVF Australia Programs in particular. The answers here are brief and may not pertain to an individual's particular case. Readers are invited to submit their own questions for publication by writing to: *LifeTimes*, IVF Australia, 137 Rowayton Avenue, Rowayton, CT 06853.

Q. Can a couple experience each step of the IVF cycle together?

A. Yes. We begin by inviting both husband and wife to attend our initial consultation.

Although most of the IVF procedures are focused on the wife regardless of the cause of infertility, mutual support during this time helps both husband and wife cope better with the stress involved. We encourage couples to approach infertility and IVF as a shared experience.

Husbands are encouraged to learn how to participate in some treatments. A husband's involvement can facilitate the treatment process, and, more importantly, enhance a shared awareness of the cycle's progress. Each couple must decide whether or not the husband will be able to attend every session. While each session is important, the inconvenience to the husband of attending may outweigh the benefit of sharing. However, husbands should be present when the eggs are retrieved. On that day, the husband will not only need to supply a specimen, but also give the wife strong and consistent emotional support.

Most couples gain strength and understanding from jointly attending meetings to learn the results of fertilization and pregnancy tests. Because the IVF cycle can uncover many hidden emotions, compassion and perspective are important at each step of the process. Infertility can be emotionally painful, but it can also be an opportunity for husband and wife to become more supportive and patient.

Q. If a couple has only female factor infertility, should the wife go through other procedures before IVF (tubal reconstruction, etc.)?

A. There are some situations (such as tubal ligation) for which a tubal reconstruction has a high success rate. Currently, most fertility experts would recommend that a woman undergo tubal reconstruction for this situation. There are other tubal diseases which have lower success rates with surgery. If both tubes are blocked at the end near the ovaries, without significant scar tissue around the ovaries, the success rate for tubal reconstruction would be approximately 30% over two years. On the other hand, if the ovaries are com-

The People of IVF Australia

▲

Patricia M. McShane, M.D., has been director of the In Vitro Fertilization Program at Brigham and Women's Hospital, Boston, where she completed her fellowship in reproductive endocrinology and infertility. She was also an assistant professor of obstetrics and gynecology at Harvard Medical School and was a researcher in reproductive immunology in collaboration with the Department of Medicine at Harvard.

Upon graduating from Tufts University School of Medicine, Dr. McShane completed her internship and residency in obstetrics and gynecology at Brigham and Women's Hospital. She is a certified diplomate of both the American Board of Obstetrics and Gynecology and its Reproductive Endocrinology Division. She is a fellow of the American College of Obstetricians and Gynecologists, and a member of the Society of Reproductive Endocrinologists, American Fertility Society. Dr. McShane has published and lectured extensively on the subjects of new reproductive technologies and infertility.

▲

Beverly J. Freeman has been Executive Director of RESOLVE, Inc., for six years, a non-profit consumer health organization with 50 chapters nationwide, serving couples with infertility problems. Upon receiving a master's degree from the University of Chicago in social service administration, she was research associate, project director and budget analyst for a variety of human service organizations.

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pletely covered in thick adhesions and the tubes are blocked, the success rate of tubal repair may be less than 5%. In these instances, the couple and the physician would have to judge whether reconstruction should be attempted. One additional factor to consider is the age of the woman. Generally, one would need to allow one to two years to determine whether a fertility operation has been successful.

In many cases of endometriosis, there may be little or no damage to the inside of the tube. Therefore, fertility surgery and medication treatment should precede in vitro fertilization attempts. However, a woman previously treated with medical or surgical therapy for recurring endometriosis need not undergo another operation.

Q. To what do you attribute today's seemingly high rate of infertility?

A. One major factor contributing to the high rate of infertility is delayed child bearing. Two large infertility studies (one completed in 1965 and the other in 1982) reported a strong correlation between a woman's age and infertility. Although there has been a recent epidemic of tubal disease and ectopic (tubal) pregnancies contributing to infertility, the rate of infertility within any given age group has remained surprisingly stable. One factor to consider is the increase in public awareness of infertility. Because more people are aware of the problem today than ten or twenty years ago infertility seems that much more prevalent.

The Emotional Side

In our last issue we briefly addressed the stress of infertility on the sexual relationship. In this issue we will explore some of the approaches useful in coping with this stress.

Before choosing IVF as a treatment, most couples have been through many months of diagnostic and treatment procedures. For most of these months, "sex on schedule," whether for gaining optimum fertility, or timing a post-coital test, has been a part of treatment. In the effort to achieve a pregnancy, what had been a pleasure becomes a chore.

Couples often try to cope with this pressure by simply ignoring it. While effective for the short-term, this approach may lead to disruption in other areas of the marriage, resulting in arguments over trivial issues when the anger actually stems from "having" to make love. Also sometimes the wife or husband think they can cope by disassociating themselves from their bodies. They are able to continue "having sex" at the correct time, but they are emotionally withdrawn from their body's experience of pleasure. Again, this approach exclusively used over time can lead to serious difficulties in reestablishing a healthy sexual relationship. Other couples may cope by joking or making light of "the job" they have to do. If joking is done with a compassionate and loving attitude, it can be an effective way of easing the stress. However, in the long run it may be unwise to develop a pattern of joking about love-making.

Perhaps one of the most effective means of coping with the sexual requirements of infertility treatment is to separate the "work" from the pleasure. It is easy, after several months of treatment, to allow "sex on schedule" to become the standard of intimacy. Remember to make the extra effort to provide time *and* space for intimacy. Listening to each others' fears and desires about all aspects of life can bring you closer. Understanding each other can help maintain the foundation for a warm and nurturing sexual relationship. Intimacy doesn't necessarily mean a candlelit dinner and seductive attitudes. In fact, these can sometimes produce an unintended increase in expectation for performance. Intimacy is more easily achieved in an atmosphere of acceptance and support.

Keep in mind that most couples cope in a combination of ways and that these approaches will vary over time. It is also likely that you and your partner may not choose the same way at the same time. If you can talk to each other, share your thoughts, and respect each other's needs, you can even use this time to enhance the intimacy of your relationship.

When To Consider IVF

The following is an excerpt from THE NEW FERTILITY AND CONCEPTION, the Essential Guide for Childless Couples, *by Dr. John J. Stangel. Dr. Stangel is a board certified reproductive endocrinologist with experience in the treatment of infertility. In addition to being medical director of the IVF Australia Program at United Hospital, Port Chester, New York, Dr. Stangel is a clinical associate professor in the Department of Obstetrics and Gynecology at New York Medical College. Dr. Stangel's private practice for 10 years in Rye, New York, has been devoted entirely to the diagnosis and treatment of infertility and other reproductive problems.*

In vitro fertilization and its variations are, in a sense, the court of last resort. They can offer the possibility of pregnancy to a woman who has extensively scarred Fallopian tubes or no tubes at all. They can be used when all other forms of treatment for infertility have been used without success.

IVF should be considered when a woman has had repeated ectopic pregnancies. After three ectopic pregnancies, the probability that a woman's next pregnancy will be ectopic is higher than the chance of its being uterine. Since the probability of an ectopic pregnancy is somewhere between 3 and 6 percent with in vitro fertilization, it is probably safer for a woman who has had several ectopic pregnancies to attempt her next pregnancy by in vitro fertilization.

There have been many advances in in vitro fertilization since the birth of Louise Brown. As we increase the number of eggs retrieved during a treatment cycle, we increase the number of embryos produced. The greater the number of embryos created, the greater probability that a woman will become pregnant.

Though in vitro fertilization is indeed the court of last resort, it is a kind court. Whereas pregnancy rates were originally 17 percent for retrieval and 20 percent for transfer....[Today's] increased pregnancy rates are due to meticulous quality control and precision in every step of egg stimulation, retrieval, and transfer. We have reason to look forward to continued success and advances in this rapidly developing mode of treatment infertility.

INDICATIONS FOR IN VITRO FERTILIZATION

A woman and her doctor should consider in vitro fertilization if she is infertile from any of the following causes:

- Absence of both Fallopian tubes:
  Congenital
  Result of surgical removal
- Failed reconstructive tubal surgery.
- Severe tubal damage or extensive intraabdominal scarring where surgery would not be successful as judged by an experienced tubal surgeon.
- After a third ectopic pregnancy.
- Antisperm antibodies — man's and/or woman's — unresponsive to medical treatment.
- Low sperm count unresponsive to conventional treatment.
- Endometriosis:—
  When infertility persists in spite of adequate surgery and/or drug treatment. (IVF has no effect on endometriosis itself.)
- Infertility of undetermined origin.
- All failed adequate infertility therapies.

(From THE NEW FERTILITY AND CONCEPTION: *The Essential Guide for Childless Couples* by John J. Stangel, M.D. Copyright ©1979, 1988 by John J. Stangel, M.D. Reprinted by arrangement with PLUME, an imprint of NAL PENGUIN INC., New York, New York.)

Program Locations

IVF Australia Program at
United Hospital
406 Boston Post Road
Port Chester, NY 10573
(914) 934-7484

IVF Australia Program—Boston at
WalthamWeston Hospital &
Medical Center
Hope Avenue
Waltham, MA 02254

From all areas including the local Boston area, call toll-free 1-800-288-4832

LifeTimes is published quarterly by IVF Australia, 137 Rowayton Ave., Rowayton, CT 06853, for physicians and their patients who are experiencing infertility. Copies are available on request. Articles may be reproduced with permission from IVF Australia.

Readers wishing to see articles on particular topics in future issues are invited to send their suggestions to the above address. Readers also are encouraged to submit letters for publication with the understanding that they may be shortened for layout purposes.

Managing Editor: Megan Dineen
Contributing Writers: Patricia Honea-Fleming, Ph.D., and Patricia M. McShane, M.D.

IVF/GIFT SURVEY

CLINIC NAME: Long Island IVF
ADDRESS: 60 North Country Road
Port Jefferson, N.Y. 11777

CONTACT PERSON: Daniel J. Kenigsberg, M.D.
PHONE NUMBER: 516 331-7575

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 4/1/89

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based XX
   (c) University based ______
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 0

6. How many other professionals participate in your clinic?
   (a) Physicians 2
   (b) Laboratory Scientists (PhDs) 0
   (c) Nurses 4
   (d) Embryo Lab Technicians/Technologists 3
   (e) Other Lab Technicians/Technologists 0
   (f) Radiology (Ultrasound) Technicians 0
   (g) Psychologists/Counselors 0
   (h) Secretaries 2
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? < 1

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 8/88 GIFT 8/88

9. How many different patients were stimulated?
1987 IVF ______ 1988/89 IVF 68 1989 IVF 44
GIFT ______ GIFT 0 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF ______ 1988/89 IVF 127
GIFT ______ GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ________ 1988/89 114

How many embryo transfer cycles were performed?
1987 ________ 1988/89 108

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ________ 1988/89 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988/89 ___ 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988/89 IVF ___ 43 %
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988/89 IVF ___ 23 %
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988/89 IVF ___ 14 %
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988/89 IVF ___ 8 %
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): IMMUNOLOGINA
1987 IVF ___ ___% 1988/89 IVF ___ ___%
GIFT ___ ___% GIFT ___ 100 % (CERVICAL) 1 PT.

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988/89 IVF ___ 25 %
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988/89 IVF ___ 43 %
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988/89 IVF ___ 26 %
GIFT ___ ___% GIFT ___ ___%

(d) 41-42: 1988/89 IVF ___ 3 %

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF - 1988 IVF 34
GIFT ___ GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF ___
GIFT ___ GIFT ___ None yet (1st due 5/89)

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 27
GIFT ___ GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF 2
GIFT ___ GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ___
GIFT ___ ___% ___

1988 IVF ___ ___% ___
GIFT ___ ___% ___

21. What are the qualifications of the director of the embryo laboratory? 4 years embryologist at EVMS/Norfolk, Va.

22. Who supervises the laboratory director? DAVID KREINER, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? YES
If the answer is yes, please specify which program.
Mouse embryo tox testing sent to EVMS - Norfolk, VA

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** applied

27. **Does the clinic train individuals in IVF or GIFT?** Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) **Physicians** 0
    (b) **Laboratory scientists (PhDs)** 0
    (c) **Embryo laboratory technicians/technologists** 1
    (d) **Nurses** 0
    (e) **Other (explain)** 0

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

Since opening in August, 1988, Long Island IVF has:

-started 127 cycles;
-performed 114 oocyte retrievals with 108 embryo transfers;
-established 34 clinical pregnancies by American Fertility Society criteria [of which 27 are on-going pregnancies];

thereby establishing a 21% success rate as per the criteria cited by the "Special to the New York Times" report dated March 10, 1987.

IVF/GIFT SURVEY

CLINIC NAME: CARE Program
ADDRESS: University of Rochester, Medical Center
Box 668, Dept. of Ob/Gyn
601 Elmwood Ave.
Rochester, N.Y. 14618
CONTACT PERSON: Margaret Graham, B.Sc., M.S.
PHONE NUMBER: 716-275-5747

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? November 1988

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based ______
   (c) University based X
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2 - one board certified Reproductive Endocrinologist; one board eligible

6. How many other professionals participate in your clinic?
   (a) Physicians ______
   (b) Laboratory Scientists (PhDs) ______
   (c) Nurses 3
   (d) Embryo Lab Technicians/Technologists 2
   (e) Other Lab Technicians/Technologists ______
   (f) Radiology (Ultrasound) Technicians 1
   (g) Psychologists/Counselors ______
   (h) Secretaries 1
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 5½

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF July, 1983 GIFT November, 1987

9. How many different patients were stimulated?
1987 IVF 59 1988 IVF 54
GIFT 2* GIFT 3*
*All Gift patients did IVF as well as Gift.

10. How many stimulation cycles were performed?
1987 IVF 74* 1988 IVF 66*
GIFT 2 GIFT 3
*includes Gift/IVF patients

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 61 1988 60

How many embryo transfer cycles were performed?
1987 51 1988 50

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 2 1988 3

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 37 57% 1988 IVF 43 84%
GIFT 0 ___% GIFT 0 ___%
Note - many patients have multifactorial infertility
(b) Endometriosis:
1987 IVF 14 22% 1988 IVF 19 37%
GIFT 2 100% GIFT 2 66%
(c) Male infertility:
1987 IVF 17 26% 1988 IVF 21 39%
GIFT 1 50% GIFT 1 33%
(d) Unexplained infertility:
1987 IVF 4 6% 1988 IVF 5 10%
GIFT 0 ___% GIFT 0 ___%
(e) Other (explain): ______________
1987 IVF ___ ___% 1988 IVF 1 2% amenorrhea - same patient
GIFT ___ ___% GIFT 1 33%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 2 3% 1988 IVF 8 15%
GIFT 0 ___% GIFT 0 ___%
(b) 31-35:
1987 IVF 26 44% 1988 IVF 24 44%
GIFT 0 ___% GIFT 0 ___%
(c) 36-40:
1987 IVF 24 41% 1988 IVF 19 35%
GIFT 1 50% GIFT 3 100%

(d) 41-45:
1987 IVF 5 8 % 1988 IVF 3 6 %
GIFT 1 50 % GIFT 0 ____ %

(e) >45:
1987 IVF 2 3 % 1988 IVF 0 ____ %
GIFT 0 ____ % GIFT 0 ____ %

16. How many clinical pregnancies were produced?
1987 IVF 4 1988 IVF 9
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 3 1988 IVF 1
GIFT ____ GIFT ____

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 4
GIFT ____ GIFT ____

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 1
GIFT ____ GIFT ____

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ____ % ____________
GIFT ____ ____ % ____________

1988 IVF 1 100% twins
GIFT ____ ____ % ____________

21. What are the qualifications of the director of the embryo laboratory? Master's Degree, 9 years tissue culture experience.

22. Who supervises the laboratory director? Dr. John H. Mattox - Division Director

23. Does the clinic participate in an external laboratory proficiency testing program? no
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** yes

27. **Does the clinic train individuals in IVF or GIFT?** yes
If the answer is yes, how many individuals in the following specialties have been trained?
    - (a) **Physicians** 1
    - (b) **Laboratory scientists (PhDs)** ______
    - (c) **Embryo laboratory technicians/technologists** 2
    - (d) **Nurses** 2
    - (e) **Other (explain)** 2 medical students and 2 undergraduate and 1 post-graduate students for Intrauterine Insemination Laboratory

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

There are many factors which determine success of an In Vitro Fertilization program. By establishing strict criteria for the selection of couples for admission to a program (i.e., no male factor or female patients over 40 years of age), the final success rate may be enhanced. The philosophy of the CARE program has always been to make treatment available to all patients who might benefit, while carefully counseling each couple as to their individual chances for success depending on their own infertility problem, and to let them make an informed choice concerning treatment. This willingness not to limit treatment only to those couples with optimum chance for success is reflected in our pregnancy rate, which, while not as high as some programs, has been, with the exception of 1987, acceptable and consistant.

IVF/GIFT SURVEY

CLINIC NAME: IVF program
ADDRESS: Division of Reproductive
Endocrinology
SUNY - Syracuse
CONTACT PERSON: Shawky Badawy M.D. [redacted]
PHONE NUMBER: 315-470-7905

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? November '88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ✓
   - (c) University based ✓
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? None

6. How many other professionals participate in your clinic?
   - (a) Physicians ______
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors ______
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? Since 1970

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF May '88 GIFT ______

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF 17
GIFT ______ GIFT ______

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF ______
GIFT ______ GIFT ______

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ________ 1988 8

How many embryo transfer cycles were performed?
1987 ________ 1988 7

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ________ 1988 0

13. What were the number and percentage of patients on IRB approved research protocols? None
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF 76% 13/76%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 6% 1/6%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 18% 3/18%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF 23.5% 4/23.5%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF 53% 9/53%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF 23.5% 4/23.5%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF N/A 1988 IVF 0
GIFT ___ GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF N/A
GIFT ___ GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF N/A
GIFT ___ GIFT ___

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF N/A
GIFT ___ GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ___
GIFT ___ ___% ___

1988 IVF N/A ___% ___
GIFT ___ ___% ___

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Radiation Biology and Biochemistry. Published work in IVF in hamster. Work on human IVF (Brigham & Women's Hospital, Boston) from November '84 until August '87.

22. Who supervises the laboratory director? Dr. Shawky Badawy

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? application submitted

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Not Yet

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

JUST '87 DATA

IVF/GIFT SURVEY

CLINIC NAME: In Vitro Fertilization-GIFT Program
ADDRESS: The North Carolina Memorial Hospital
Department of Obstetrics and Gynecology
UNC Medical School Box 7570
Chapel Hill, NC 27599-7570
CONTACT PERSON: Luther M. Talbert, M.D., Program Director
PHONE NUMBER: (919) 966-1150, (919) 966-5438

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

***** 1. The following data is current through what date? 1/1/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    (a) Private ____
    (b) Community hospital based ____
    (c) University based x
    (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2 + 2 Fellows

6. How many other professionals participate in your clinic?
    (a) Physicians 0
    (b) Laboratory Scientists (PhDs) 1
    (c) Nurses 2.5
    (d) Embryo Lab Technicians/Technologists 2
    (e) Other Lab Technicians/Technologists 0
    (f) Radiology (Ultrasound) Technicians 0
    (g) Psychologists/Counselors 0
    (h) Secretaries 3
    (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? 20

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1986

****1988 Data is still being compiled (due to lack of computer availability).

9. How many different patients were stimulated?
1987 IVF 129 1988 IVF ___
GIFT 23 GIFT ___

10. How many stimulation cycles were performed?
1987 IVF 195 1988 IVF ___
GIFT 25 GIFT ___

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 127 1988 ___

How many embryo transfer cycles were performed?
1987 104 1988 ___

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 25 1988 ___

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 146 ___% 1988 IVF ___ ___%
GIFT 0 ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 29 ___% 1988 IVF ___ ___%
GIFT 8 ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF 5 ___% 1988 IVF ___ ___%
GIFT 2 ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF 12 ___% 1988 IVF ___ ___%
GIFT 14 ___% GIFT ___ ___%
(e) Other (explain): ___
1987 IVF 3 ___% 1988 IVF ___ ___%
GIFT 1 ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 33 20% 1988 IVF ___ ___%
GIFT 5 20% GIFT ___ ___%
(b) 31-35:
1987 IVF 60 36% 1988 IVF ___ ___%
GIFT 8 32% GIFT ___ ___%
(c) 36-40:
1987 IVF 69 41% 1988 IVF ___ ___%
GIFT 10 40% GIFT ___ ___%

(d) 41-45:
1987 IVF 5 3% 1988 IVF ___ ___%
GIFT 1 1% GIFT ___ ___%

(e) >45:
1987 IVF 0 ___% 1988 IVF ___ ___%
GIFT 0 ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 22 1988 IVF ___
GIFT 5 GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 15 1988 IVF ___
GIFT 3 GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 12 1988 IVF ___
GIFT 2 GIFT ___

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF ___
GIFT 1 GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 7 46% 1 triplet, 6 twins
GIFT ___ ___% ___

1988 IVF ___ ___% ___
GIFT ___ ___% ___

21. What are the qualifications of the director of the embryo laboratory? Ph.D: Physiology Kent State, 1984.
3 yrs as Post-Doctorate with Michael O'Rand, Ph.D.
UNC Dept. of Anatomy 1984-87.

22. Who supervises the laboratory director? Luther M. Talbert, M.D.
Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? No.
If the answer is yes, please specify which program. ___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes.

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes.

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes.

27. Does the clinic train individuals in IVF or GIFT? Yes. If the answer is yes, how many individuals in the following specialties have been trained?
    - (a) Physicians 5
    - (b) Laboratory scientists (PhDs) 1
    - (c) Embryo laboratory technicians/technologists 6
    - (d) Nurses 30
    - (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

RECEIVED
DEC 19 1988
Hon. Ron Wyden

IVF/GIFT SURVEY

CLINIC NAME: Duke University Medical Center
ADDRESS: Box 3527
Durham, NC 27710

CONTACT PERSON: William Dodson, M.D.
PHONE NUMBER: (919) 684-5327

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/1/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ____
   - (b) Community hospital based ____
   - (c) University based X
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   - (a) Physicians 5
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 0
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 3
   - (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1985

9. How many different patients were stimulated?
1987 IVF 56 1988 IVF 65
GIFT 10 GIFT 9

10. How many stimulation cycles were performed?
1987 IVF 71 1988 IVF 75
GIFT 10 GIFT 11

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 50 1988 52

How many embryo transfer cycles were performed?
1987 45 1988 48

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 9 1988 7

13. What were the number and percentage of patients on IRB approved research protocols?
1987 10 15 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 33 59 % 1988 IVF 29 45 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 20 36 % 1988 IVF 28 43 %
GIFT 7 70 % GIFT 7 78 %
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 5 8 %
GIFT 1 10 % GIFT 2 22 %
(d) Unexplained infertility:
1987 IVF 3 5 % 1988 IVF 3 5 %
GIFT 2 20 % GIFT 0 0 %
(e) Other (explain): ______
1987 IVF ___ ___ % 1988 IVF ___ ___ %
GIFT ___ ___ % GIFT ___ ___ %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 13 23 % 1988 IVF 17 26 %
GIFT 2 20 % GIFT 3 33 %
(b) 31-35:
1987 IVF 30 54 % 1988 IVF 36 55 %
GIFT 6 60 % GIFT 5 56 %
(c) 36-40:
1987 IVF 12 21 % 1988 IVF 12 19 %
GIFT 2 20 % GIFT 1 11 %

(d) 41-45:
1987 IVF 1 2 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 8 1988 IVF 6
GIFT 1 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 4 1988 IVF 1
GIFT 1 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 5
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 2 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 25 % Twins
GIFT 1 100 % Quadruplets

1988 IVF 2 33 % Two sets of quadruplets
GIFT 1 100 % Twins

21. What are the qualifications of the director of the embryo laboratory? Ph. D. in gamete physiology

22. Who supervises the laboratory director? William Dodson, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 14
    (b) Laboratory scientists (PhDs) 1
    (c) Embryo laboratory technicians/technologists 4
    (d) Nurses 2
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The vast majority of patients with patent oviducts are given at least one, and usually several, attempts to conceive with superovulation and intrauterine insemination before beginning a cycle of IVF or GIFT.

IVF/GIFT SURVEY

CLINIC NAME: The North Carolina Reproductive Center
ADDRESS: P.O. Box 4052
Greensboro, NC 27404

CONTACT PERSON: Elizabeth Stanley
PHONE NUMBER: 919-373-8555

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the never clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ____
   - (b) Community hospital based ✓
   - (c) University based ____
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   - (a) Physicians ____
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 5
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists ____
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 1
   - (i) Other (specify) ____

7. How many years has your infertility clinic been in operation? 2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 3/87 GIFT —

9. How many different patients were stimulated?
1987 IVF 6 1988 IVF 5
GIFT 0 GIFT 0

10. How many stimulation cycles were performed?
1987 IVF 6 1988 IVF 9
GIFT 0 GIFT 0

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 6 1988 5

How many embryo transfer cycles were performed?
1987 6 1988 4

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 3 50% 1988 IVF 2 40%
GIFT ___ ___% GIFT 0 ___%
(b) Endometriosis: 16
1987 IVF 1 ___% 1988 IVF 1 20%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF 1 17% 1988 IVF 1 20%
GIFT ___ ___% GIFT 0 ___%
(d) Unexplained infertility:
1987 IVF 1 17% 1988 IVF 1 20%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): [illegible]
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 1 16% 1988 IVF 1 20%
GIFT 0 ___% GIFT ___ ___%
(b) 31-35:
1987 IVF 4 67% 1988 IVF 4 80%
GIFT 0 ___% GIFT ___ ___%
(c) 36-40:
1987 IVF 4 ___% 1988 IVF 0 ___%
GIFT [illegible] ___% GIFT ___ ___%

(d) 41-45:
1987 IVF 1 17% 1988 IVF ___ ___%
GIFT 0 0 % GIFT ___ ___%
(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 1 1988 IVF 1 ~~[illegible]~~ know final tests yet
GIFT ___ GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 1 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 2*
GIFT ___ GIFT ___
* One of these pregnancies occur after IVF as a result of some corrective things done at surgery (lysis of adhesions)

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT ___ GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 16% single
GIFT ___ ___%

1988 IVF ___ ___% all are continuing pregnancies at this pt
GIFT ___ ___%

21. What are the qualifications of the director of the embryo laboratory? PHD and experience in many IVF programs

22. Who supervises the laboratory director? no-one

23. Does the clinic participate in an external laboratory proficiency testing program? yes
If the answer is yes, please specify which program.
Norfolk

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? no

27. Does the clinic train individuals in IVF or GIFT? no
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ______
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ______
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

We are a very small private IVF clinic at this point We have had a good pregnancy rate and have very dedicated individuals. We will soon be doing ultrasound capture as well as freezing of embryos we hope. We also will be doing gift as needed.

IVF/GIFT SURVEY

CLINIC NAME: Women's Specialty Center -(Charlotte Mem. Hosp.)
ADDRESS: 1901 Brunswick Avenue
Charlotte, N.C. 28207

CONTACT PERSON: Dr. Richard Wing
PHONE NUMBER: 704-343-3400

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? ____

2. Does your clinic perform IVF/GIFT treatments? yes - as satellite for the UNC IVF Program, Chapel Hill N.C under Dr. Luther Talbert
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

All statistics are summarized under one institution.
RWing MD

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ✓
   (b) Community hospital based ✓
   (c) University based ____
   (d) Other (explain) Satellite program

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   (a) Physicians 3
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 5
   (d) Embryo Lab Technicians/Technologists ____
   (e) Other Lab Technicians/Technologists 3
   (f) Radiology (Ultrasound) Technicians ____
   (g) Psychologists/Counselors 1
   (h) Secretaries 2
   (i) Other (specify) 3

7. How many years has your infertility clinic been in operation? 6 yrs

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF ____ GIFT ____

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF _______
GIFT _____ GIFT ______

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF _______
GIFT _____ GIFT _____

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ________ 1988 ________

How many embryo transfer cycles were performed?
1987 ________ 1988 ________

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ________ 1988 _________

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ __%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ________________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

19. How many ectopic pregnancies resulted?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ______________________
GIFT ___ ___% ______________________

1988 IVF ___ ___% ______________________
GIFT ___ ___% ______________________

21. What are the qualifications of the director of the embryo laboratory? ______________________
____

22. Who supervises the laboratory director? ______________________

23. Does the clinic participate in an external laboratory proficiency testing program? ______________________
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? ______________________

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? _____

26. Is the clinic a member of the Society for Assisted Reproductive Technology? ___ ___________

27. Does the clinic train individuals in IVF or GIFT? ______ If the answer is yes, how many individuals in the following specialties have been trained?
    - (a) Physicians ________
    - (b) Laboratory scientists (PhDs) _______
    - (c) Embryo laboratory technicians/technologists _____
    - (d) Nurses _______
    - (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Akron City Hospital In Vitro Fertilization Program
ADDRESS: 525 E. Market Street
Akron, Ohio 44309

CONTACT PERSON: Nicholas J. Spirtos, D.O. - Director
PHONE NUMBER: (216) 375-3585

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/16/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1 - Same individual as above

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 0
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians 4
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 2
   - (i) Other (specify) Residents and Medical Students on Rotational Assignment

7. How many years has your infertility clinic been in operation? 3

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF June 1985 GIFT January 1987

9. How many different patients were stimulated?
1987 IVF 53 1988 IVF 65
GIFT 1 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 70 1988 IVF 90
GIFT 1 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 44 1988 52

How many embryo transfer cycles were performed?
1987 28 1988 42

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 71 100 % 1988 91 100 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 25 58.1% 1988 IVF 31 62 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 2 4.7% 1988 IVF 8 16 %
GIFT 0 0 % GIFT 0 0 %
(c) Male infertility:
1987 IVF 10 23.3% 1988 IVF 9 18 %
GIFT 0 0 % GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 2 4.7% 1988 IVF 1 2 %
GIFT 0 0 % GIFT 0 0 %
(e) Other (explain): Empty Follicle Syndrome, DES Exposure
1987 IVF 4 9.3% 1988 IVF 1 2 %
GIFT 1 100 % GIFT 2 100%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 23 53.5% 1988 IVF 25 50 %
GIFT 0 0 % GIFT 0 0 %
(b) 31-35:
1987 IVF 12 27.9% 1988 IVF 16 32 %
GIFT 1 100 % GIFT 2 100 %
(c) 36-40:
1987 IVF 8 18.6% 1988 IVF 8 16 %
GIFT 0 0 % GIFT 0 0 %

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 1 2 %
GIFT 0 0 % GIFT 0 0 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 10 1988 IVF 12
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 2 1988 IVF 10
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 1 1988 IVF ~~2~~ 10
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 50 % 1 - set of twins
GIFT 0 0 %

1988 IVF 2 20 % 1 - set of twins; 1 - set of triplets
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? Bachelor of Science, Biology; 2 years In Vitro Fertilization research with primates; 3 years Human In Vitro Fertilization Laboratory experience

22. Who supervises the laboratory director? Reproductive Endocrinologist

23. Does the clinic participate in an external laboratory proficiency testing program? Yes,
If the answer is yes, please specify which program.
Old Dominion University, Embryology Laboratory, Norfolk, VA

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Societv for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

All quoted statistics for 1988 are calculated for those individuals who completed oocyte retrieval by November 16, 1988.

GIFT statistics are only quoted for those individuals who had a GIFT procedure ONLY performed. Individuals who had IVF/GIFT performed in the same cycle are included in the overall IVF statistical quotes.

IVF/GIFT SURVEY

CLINIC NAME: Midwest Reproductive Institute
ADDRESS: c/o Nichols Vorys, M.D.
1492 East Broad Street
Suite 1203
Columbus, Ohio 43205
CONTACT PERSON: Kimberly Lewis, MLT(ASCP)
PHONE NUMBER: (614) 253-0003

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/1/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private X
   (b) Community hospital based ________
   (c) University based ________
   (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
   (a) Physicians 0
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 3
   (d) Embryo Lab Technicians/Technologists 1
   (e) Other Lab Technicians/Technologists 5
   (f) Radiology (Ultrasound) Technicians 2
   (g) Psychologists/Counselors 0
   (h) Secretaries 2
   (i) Other (specify) 1 (Administrative Supervisor)

7. How many years has your infertility clinic been in operation? 20

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 1984 GIFT 1986

9. How many different patients were stimulated?
1987 IVF 31 1988 IVF 34
GIFT 41 GIFT 47

10. How many stimulation cycles were performed?
1987 IVF 37 1988 IVF 43
GIFT 47 GIFT 61

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 26 1988 27

How many embryo transfer cycles were performed?
1987 16 1988 36

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 13 1988 36

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 13 18% 1988 IVF 16 20%
GIFT 2 3% GIFT 5 6%
(b) Endometriosis:
1987 IVF 7 10% 1988 IVF 18 22%
GIFT 16 22% GIFT 17 21%
(c) Male infertility:
1987 IVF 12 17% 1988 IVF 21 25%
GIFT 26 36% GIFT 26 32%
(d) Unexplained infertility:
1987 IVF 5 7% 1988 IVF 1 1%
GIFT 7 10% GIFT 4 5%
(e) Other (explain): see appendix A
1987 IVF 5 7% 1988 IVF 4 5%
GIFT 5 7% GIFT 9 11%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 16 22% 1988 IVF 12 15%
GIFT 17 24% GIFT 19 23%
(b) 31-35:
1987 IVF 9 13% 1988 IVF 14 17%
GIFT 14 19% GIFT 19 23%
(c) 36-40:
1987 IVF 6 8% 1988 IVF 7 9%
GIFT 8 11% GIFT 8 10%

(d) 41-45:
1987 IVF 0 ___% 1988 IVF 2 3%
GIFT 2 3% GIFT 0 ___%
(e) >45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF 2 1988 IVF 6
GIFT 3 GIFT 8

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 3 GIFT 3

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 2
GIFT 0 GIFT 5

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___% ________________
GIFT 0 ___% ________________

1988 IVF 0 ___% ________________
GIFT 1 12.5% twins - male/female
calculated from continuing pregnancies for 1988

21. What are the qualifications of the director of the embryo laboratory? Ph.D., Endocrinology, Immunology, Director of College of American Pathologists certified laboratory

22. Who supervises the laboratory director? Consulting Medical Director

23. Does the clinic participate in an external laboratory proficiency testing program? YES
If the answer is yes, please specify which program.
College of American Pathologists

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? YES

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 6
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 3
    (d) Nurses 1
    (e) Other (explain) 0

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

SEE ATTACHED.

MIDWEST REPRODUCTIVE INSTITUTE
1492 East Broad Street
Suite 1203
Columbus, Ohio 43205

APPENEDX A

Page 2, questions 14 and 15:	Percentages were calculated using the total number of patients for the corresponding year. 1987 Total Patients = 72 1988 Total Patients = 81
Page 2, question 14 e:	Explanation of other types of patient diagnosis:
1987 IVF Total 5	Anovulation = 5
1987 GIFT Total 5	Cervical Cancer = 1 DES Exposure = 1 Hyperandrogenism = 1 Stein Leventhal Syndrome = 2
1988 IVF Total 4	Hirsutism = 1 DES Exposure = 3
1988 GIFT Total 9	Hirsutism = 1 DES Exposure = 1 Stein Leventhal Syndrome = 6 Cushings Disease = 1

CURRICULUM VITAE

NICHOLS VORYS, M.D.

DATE OF BIRTH: August 18, 1924

PLACE OF BIRTH: Lancaster, Ohio

PRESENT POSITION:

1. Consulting Medical Director, Midwest Reproductive Institute
   1409 Hawthorne Avenue, Columbus, Ohio 43203

2. Director, DxRx, Inc.
   1492 East Broad Street, Suite 1203, Columbus, Ohio 43203

3. Clinical Associate Professor, Department of Obstetrics and Gynecology, The Ohio State University College of Medicine,
   410 West 10th Avenue, Columbus, Ohio 43210

EDUCATION:

1948	B.S.; Dartmouth College, Hanover, New Hampshire
1953	M.D.; Jefferson Medical College, Philadelphia, Pennsylvania
1958	M.Sc.; The Ohio State University, Columbus, Ohio

PRESENT AND PAST APPOINTMENTS AND/OR EMPLOYMENT:

1948 - 1949	Research Associate - Battelle Memorial Institute Columbus, Ohio
1953 - 1954	Internship, Pennsylvania Hospital, Philadelphia, Pennsylvania
1954 - 1958	Residency, The Ohio State University Hospital, Columbus, Ohio
1958 - 1966	Assistant Professor, Department of Obstetrics and Gynecology, The Ohio State University, Columbus, Ohio
1961	Diplomat, American Board of Obstetrics and Gynecology
1961 - 1968	Director, Reproductive Endocrinology, Department of Obstetrics and Gynecology, The Ohio State University, Columbus, Ohio
1963 - 1968	Co-Director, Obstetrical and Gynecological Endocrinology, NIH Training Grant, The Ohio State University, Columbus, Ohio
1966 - 1968	Associate Professor, Department of Obstetrics and Gynecology, The Ohio State University, Columbus, Ohio
1966 - 1971	Vice President and Director of Medical Affairs, The Mogul Corporation, Cleveland, Ohio
1971 - 1973	Vice President and Director of Research, Searle Reference Laboratories, Columbus, Ohio
1968 - 1978	President, Gynecology Associates, Inc., Clinical Associate Professor, Department of Obstetrics & Gynecology

CURRICULUM VITAE

Charles Bayard Paschall, III, Ph.D.

Work: 1409 Hawthorne Avenue
Columbus, Ohio 43203
(614) 253-0003

Home: 332 Westland Avenue
Bexley, Ohio 43209
(614) 258-8124

OBJECTIVE: Application specific

SUMMARY: Initiated and directed the establishment and accreditation of an independent diagnostic and therapeutic laboratory by the College of American Pathologists.

Comprehensive communication skills.

Five years experience in the development of micro-computer database and information processing application systems.

Eight additional years of experience in statistical design/modeling, basic and applied experiment design, and report writing.

EMPLOYMENT:

1982-Present Midwest Reproductive Institute
1409 Hawthorne Avenue, Columbus, Ohio 43203
College of American Pathologists accredited Director

1) De novo development of an all encompassing teritary care andrology, in vitro fertilization/GIFT and endocrine laboratory;
2) the design and implementation of quality control and quality assurance procedures and protocols;
3) supervision of all staff employees;
4) comprehensive financial management;
5) marketing;
6) grant and contract acquisition; and
7) weekly, monthly, and quarterly presentations of Grand Round lectures to medical residents and attending staff physicians covering all aspects of reproductive biology.

1978-Present
Nichols Vorys, M.D.
Infertility and Gynecology, Inc.
1492 East Broad Street, Columbus, Ohio 43205
Director of Clinical Research and Development

1) All aspects of patient office management;
2) Design of retro- and prospective research projects.

1976 - 1978
University College
The Ohio State University, Columbus, Ohio 43201
Graduate Academic Advisor

1) Course development;
2) Student orientation, academic advising and counselling.

1974 - 1978
H. C. Hines, Ph.D.
The Department of Dairy Science
The Ohio State University, Columbus, Ohio 43201
Several Graduate Academic, Teaching and Research Associateships

1) Teaching and research assistant;
2) Laboratory assistant;
3) Lecture/seminar presentations.

EDUCATION:

1983
Ph.D.; Immunology and Endocrinology
The Ohio State University, Columbus, Ohio

1979
M.Sc.; Reproductive Physiology/Endocrinology
The Ohio State University, Columbus, Ohio

1971
B.A.; Economics
Tufts University, Boston, Massachusetts

PROFESSIONAL ASSOCIATIONS and HONOR SOCIETIES:

American Association for the Advancement of Science
American Fertility Society
American Society of Andrology
American Society for the Immunology of Reproduction
Phi Kappa Phi Honor Society
Sigma Xi Honor Society .

PERSONAL:

Date of Birth: November 19, 1949; Wilmington, Delaware
Marital Status: Married; two children

EXTRA-CURRICULAR ACTIVITIES:

Aviation
Sailing
Member of Rotary International

REFERENCES and CERTIFICATIONS:

Available upon request

PUBLICATIONS, LECTURES, and PRESENTATIONS:

Available upon request

Revised 10/88

Kimberly S. Lewis, MLT(ASCP)
199 South Ardmore Road
Bexley, Ohio 43209
(614) 237-6276

CURRICULUM VITAE

Date of Birth: August 1, 1954; Mobile, Alabama
Marital Status: Divorced, two children.

EDUCATION:

1974	Associate Degree in Laboratory Medicine Columbus Technical Institute Columbus, Ohio
1974	American Society of Clinical Pathologists Board of Registry: MLT Certification
1986	Eye Bank Association of America: Certification as Eye Bank Technician

EMPLOYMENT:

12/87-Present	Midwest Reproductive Institute 1409 Hawthorne Avenue Columbus, Ohio 43203 Supervisor of GIFT/IVF Laboratory
9/86-12/87	Lions Eye Bank The Ohio State University 456 West Tenth Avenue Columbus, Ohio 43210 Tissue Coordinator Chief Eye Bank Technician
7/85-8/86	Braxton County Hospital Gassaway, West Virginia 26624 Medical Laboratory Technician All areas of clinical laboratory
9/77-5/83	Summersville Memorial Hospital Summersville, West Virginia Medical Laboratory Technician All areas of clinical laboratory
4/72-9/77	Children's Hospital 700 Children's Drive Columbus, Ohio 43206 Medical Laboratory Technician Hematology, chemistry

3/74-9/74 Saint Anthony Medical Center
1492 East Broad Street
Columbus, Ohio 43205
Medical Laboratory Technician
Internship for academic credit

PRESENTATIONS AND LECTURES:

2/87 "Approaching the Family for Tissue Donations"
The Fawcett Center for Tomorrow
Three one-day seminars for area Nurses, Social Workers, and Chaplains dealing with donor critera of tissue donation as well as how to approach a family with this request.

8/87 Published brochure with Dr. Larry Vande Creek, Chaplain and Professor of Family Medicine at The Ohio State University: "...for the FAMILY". Brochures are being used to aid families in their decision about tissue donation from a deceased loved one.

10/87 "Review of Enucleation Procedures and Reconstruction of Orbits for Funeral Directors"
Franklin County Coroners Office
One day seminar for review of Eye Bank Procedures for Funeral Directors who acted as Volunteer Enucleators for the Lions Eye Bank.

11/87 "Extending Corneal Storage with 2.5% Chondroitin Sulfate (K-Sol)"
The Academy of Ophthalmology, Dallas, TX.
Research concerning the transfer of M-K Media stored corneas to K-Sol Media. Presented by Richard H. Keates, MD, Medical Director of the Lions Eye Bank.

11/86 to 12/87 Presentations given to Lions Clubs as well as Civic Organizations on a regular basis about the Eye Bank. These presentations were for informational purposes. Also gave inservices to Medical Professionals on as routine basis as part of nursing education about tissue donations.

MEETINGS, SEMINARS AND SYMPOSIUMS:

1979 One day workshops with The State Hygenic Laboratory, Charleston, West Virginia
-Streptococcus Screening in Throat Cultures
-Differentiating Staphlacoccus from Streptococcus
-Identification of Enterbactiereacea
-Review of Kirby-Bauer Method of Sensitivity
-Identification of Niesseria gonorrheae

1985 and 1986	1/2 day lectures: Dr. Bob Caldwell, Pathologist CAMC Memorial Division, Charleston, West Virginia -Laboratory Diagnosis of AIDS -Dipplococcus pneumonese - A Comparison of Chest X-rays and Gram Stains -Electrolyte Imbalance in Hypertension -Use of "MicroScan" for Bacteria ID and MIC Determinations -Laboratory Diagnosis of Hepatitis-B
1986	Glenville State College Glenville, West Virginia "On Death and Dying" 2 month Sociology course
1986	Eye Bank Association of America 21st Annual Meeting St. Louis, Missori
1987	1/2 day lecture given by Epidemiologists at The Ohio State University Hospital AIDS Precautions for Health Care Workers: Recommendations from CDC
1988	3rd Annual Meeting of IVF Coordinators Scottsdale, Arizona
1988	IVF-ET Comprehensive Update Santa Barbara, California

IVF/GIFT SURVEY

CLINIC NAME: Riverside Reproductive Services
ADDRESS: 3726 K Olentangy River Road
Columbus, Ohio 43214

CONTACT PERSON: Jill Franks, RN IVF/GIFT Nurse Coordinator
PHONE NUMBER: 614-261-5032

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 9/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based x
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians ______
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 3
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 1 year

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 10/1/87 GIFT 6/1/87

9. How many different patients were stimulated?
1987 IVF 11 1988 IVF 27
GIFT 14 GIFT 62

10. How many stimulation cycles were performed?
1987 IVF 12 1988 IVF 51
GIFT 16 GIFT 102

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 10 1988 38

How many embryo transfer cycles were performed?
1987 9 1988 31

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 13 1988 72

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 6 54.5 % 1988 IVF 7 26.9 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 1 9 % 1988 IVF 1 3.8 %
GIFT 3 21.4 % GIFT 19 30.1 %
(c) Male infertility:
1987 IVF 3 27 % 1988 IVF 13 50 %
GIFT 4 28.5 % GIFT 31 49.2 %
(d) Unexplained infertility:
1987 IVF 1 9 % 1988 IVF 3 11.5 %
GIFT 7 50 % GIFT 13 20.6 %
(e) Other (explain): ovarian failure
1987 IVF 0 0 % 1988 IVF 2 7.7 %
GIFT 0 0 % GIFT 0 0 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 3 27.2 % 1988 IVF 8 30.8 %
GIFT 5 35.7 % GIFT 17 27.4 %
(b) 31-35:
1987 IVF 2 18.2 % 1988 IVF 11 42 %
GIFT 8 57.3 % GIFT 26 41 %
(c) 36-40:
1987 IVF 4 36.4 % 1988 IVF 5 23.1 %
GIFT 1 7 % GIFT 19 30.6 %

(d) 41-45:
1987 IVF 2 18.2% 1988 IVF 1 3.8 %
GIFT 0 0 % GIFT 1 1.6 %
(e) >45:
1987 IVF 0 0 % 1988 IVF ___ ___ %
GIFT 0 0 % GIFT ___ ___ %

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 5
GIFT 3 GIFT 18

17. How many women delivered live infants from IVF/GIFT?
1987 IVF N/A 1988 IVF 1
GIFT N/A GIFT 3

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF N/A 1988 IVF 1
GIFT N/A GIFT 6

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 % ___
GIFT 0 0 % ___

1988 IVF 0 0 % ___
GIFT 0 0 % ___

21. What are the qualifications of the director of the embryo laboratory? MS, PhD in Reproductive Biology, Dairy Science Dept, The Ohio State Univ.; 1 yr. post-doctorate OB-GYN Dept, The Ohio State Univ.; formerly, 5 years director of andrology lab and 4 years director of IVF lab.

22. Who supervises the laboratory director? Medical Director

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Pending

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
- **(a) Physicians** _______
- **(b) Laboratory scientists (PhDs)** _______
- **(c) Embryo laboratory technicians/technologists** _______
- **(d) Nurses** _______
- **(e) Other (explain)** _______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The IVF-ER Program at Riverside Methodist Hospitals is a newly formed clinic comprised of experienced IVF professionals from several successful programs. All laboratory and nursing staff are dedicated full-time to the program and have no other duties. A special interest in male factor-related infertility has resulted in a significant proportion of both IVF and GIFT patients (50%) with this problem, which has adversely affected the overall success rate. Embryo cryopreservation and a donor oocyte program are also clinically active.

IVF/GIFT SURVEY

CLINIC NAME: The Fertility Institute
ADDRESS: 40 N Grand Suite 302 Ft. Thomas KY 41075
2800 Winslow Suite 203 Cincinnati OH 45206
4452 Eastgate Blvd Suite 302 Cincinnati OH 45245

CONTACT PERSON: Lynne A Mahony, Marketing Director (Ft. Thomas KY address)
PHONE NUMBER: 606-441-1201

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11-21-88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private x
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 0

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   - (a) Physicians ________
   - (b) Laboratory Scientists (PhDs) ________
   - (c) Nurses 8
   - (d) Embryo Lab Technicians/Technologists ________
   - (e) Other Lab Technicians/Technologists 6
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors ________
   - (h) Secretaries 2
   - (i) Other (specify) Business Manager / Quality Assurance Coordinator / Surgery Scheduler / Marketing Director / Billing Personnel (2)

7. How many years has your infertility clinic been in operation? 3

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 11-28-86 GIFT 1-9-86

9. How many different patients were stimulated?
1987 IVF 10 1988 IVF 1
GIFT 33 GIFT 34

10. How many stimulation cycles were performed?
1987 IVF 10 1988 IVF 1
GIFT 46 GIFT 38

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 10 1988 1

How many embryo transfer cycles were performed?
1987 10 1988 1

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 46 1988 38

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:

NOT READILY AVAILABLE

(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ______________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:

NOT READILY AVAILABLE

(a) <31:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 1 1988 IVF 0
GIFT 12 GIFT 9

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 6 GIFT [redacted]5

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 2

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 0
GIFT 1 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0%
GIFT 1 16.6% triplets

1988 IVF 0 0%
GIFT 3[redacted] 60.0% 1 set triplets 2 sets twins

21. What are the qualifications of the director of the embryo laboratory?
Board Certified OB Gyn, FACOG

22. Who supervises the laboratory director? —

23. Does the clinic participate in an external laboratory proficiency testing program? no
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? _____

26. Is the clinic a member of the Society for Assisted Reproductive Technology? no

27. Does the clinic train individuals in IVF or GIFT? no
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

1)GIFT Statistics

GIFT CYCLES	TOTAL	1986	1987	1988
# of cycles	108	24	46	38
# clincical preg	29	8	12	9
Ectopic	1		1	
SAB	11	3	4	4
D & C	1		1	
mothers delivd	14	5	6	3
babies born	20	5	9	6
yet undeliverd	2			2

2)Physician Qualifications (attached)

3)Stimulation Protocols (attached)

METRODIN THERAPY

PROTOCOL FOR GIFT

PATIENT NAME:____

DIAGNOSIS:____

1. Day 1 of cycle(first day of period) - Follicular scan, and 4 amps of Pergonal or Metrodin.

A follicular scan will be done to insure that there are no unruptured follicles kept from previous cycle. Follicles are clear fluid filled cysts where the ova or eggs are located, usually one egg is contained in each follicle. The size of the follicle will tell the maturity level of the ova.

In preparation for the scan, it is necessary to empty your bladder one hour prior to the time of the scan and drink two 12 oz. glasses of water or other liquids 1 hour prior to the scan. Do not urinate until after the scan has been performed.

2. Day 2-7 You will take Serophene 50 mg. 2 tablets a day. This is an oral medication and it should be taken in the a.m.

3. Day 2- You will receive 2 amps of Metrodin, then days 3-7 you will receive 1 amp of Metrodin.

4. Day 6 of period - Follicular scan to evaluate status of follicles.

5. Day 8 of period - Follicular scan and possible injection depending on results of the follicular scan.

6. Days 9-12 of period - Follicular scan and possible injection depending on rate of development.

When follicles reach 17-18 mm in size, you will be sent to Jewish Hospital for Pre-Admission Testing. This testing is done at Jewish Hospital on Level A at the Outpatient Dept. The test you need are CBC (complete blood count), UA (urinalysis), T&S (type and screen), and Serum for semen preparation.

PROTOCOL FOR GIFT

PATIENT:____________________________________

HOME PHONE:_____________WORK PHONE__________

1. TSH LEVEL:________
   PROLACTIN LEVEL:______
   SIMS HUNAR TEST_______

   LAPAROSCOPIC EXAM:

   TUBAL FACTOR:__________________________

   OVARIAN FACTOR:________________________

2. MALE FACTOR:______________________________

   COUNT:_______________

   MOBILITY:____________

   DATE:________________

   PHYSICAL:____________

   DIAGNOSIS:______________________________

3. NOTIFY JEWISH HOSPITAL ON DAY 7 OF CYCLE. THIS GIVES THE HOSPITAL ADVANCE KNOWLEDGE OF UP COMING SURGERY.

PROTOCOL FOR GIFT

* When follicles reach maturation (19-20 mm in diameter) the ova (egg) will be released with the help of an injection called HCG. Surgery is scheduled for 30-34 hours after this injection depending on follicular scan findings.

PREPARATION FOR SURGERY:

1. Do not eat or drink anything 12 before sheduled surgery.
2. Present to Jewish Hospital outpatient department, located on Level A, 2 hours before surgery.
3. Have husband collect semen specimen just before leaving home in sterile container. Keep specimen at body temperature. It is to be given to the infertility lab personnel on the 4th floor.
4. After surgery, remain as inactive as possible for 24-36 hours so not to dislodge gametes. Pain medication will not affect fertilization.
5. Use progesterone suppositories 100 mg. every night intravaginally beginning 2 days after the procedure. You can expect some mild vaginal bleeding.
6. Present for Beta HCG (pregnancy test) 12-14 days after procedure. Refrain from intercourse for one week after surgery.

IVF/GIFT SURVEY

CLINIC NAME: Jewish Hospital of Cincinnati.
ADDRESS: 3200 Burnet Ave.
Cincinnati, Ohio
45229

CONTACT PERSON: Dr Sheldon P Pelchovitz
PHONE NUMBER: (513) 221-3062

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? _____

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private _______
   (b) Community hospital based ✓
   (c) University based _______
   (d) Other (explain) _______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 0

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 6

6. How many other professionals participate in your clinic?
   (a) Physicians 0
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 4
   (d) Embryo Lab Technicians/Technologists 1
   (e) Other Lab Technicians/Technologists 0
   (f) Radiology (Ultrasound) Technicians 3
   (g) Psychologists/Counselors 1
   (h) Secretaries 1
   (i) Other (specify) _______

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 11/83 GIFT _______

9. How many different patients were stimulated?
1987 IVF 5 1988 IVF 5
GIFT 15 GIFT 12

10. How many stimulation cycles were performed?
1987 IVF 7 1988 IVF 5
GIFT 15 GIFT 15

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 3 1988 5

How many embryo transfer cycles were performed?
1987 3 1988 5

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 15 1988 7

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 5 100% 1988 IVF 5 100%
GIFT ___ ___% GIFT 0 0%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 5 33% GIFT 6 50%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 10 66% GIFT 6 50%
(e) Other (explain): ___
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%
(b) 31-35:
1987 IVF 3 40% 1988 IVF 3 60%
GIFT 5 33% GIFT 6 50%
(c) 36-40:
1987 IVF 2 40% 1988 IVF 2 40%
GIFT 10 66% GIFT 4 30%

(d) 41-45:
1987 IVF 1 20 % 1988 IVF ___ ___ %
GIFT ___ ___ % GIFT 2 20 %

(e) >45:
1987 IVF 0 ___ % 1988 IVF 0 ___ %
GIFT 0 ___ % GIFT 0 ___ %

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 2
GIFT 2 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___ % ______________________
GIFT ___ ___ % ______________________

1988 IVF ___ ___ % ______________________
GIFT ___ ___ % ______________________

21. What are the qualifications of the director of the embryo laboratory? Past - masters degree microbiology
Present - PhD embryology

22. Who supervises the laboratory director? AVP Diagn. Service

23. Does the clinic participate in an external laboratory proficiency testing program? no
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? no

26. Is the clinic a member of the Society for Assisted Reproductive Technology? no

27. Does the clinic train individuals in IVF or GIFT? no
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 0
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 0
    (d) Nurses 0
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Center for Reproductive Health
ADDRESS: University of Cincinnati
College of Medicine
Bethesda at Eden Ave (ML 456)
Cincinnati, Ohio 45267
CONTACT PERSON: Marcelle I Cedars M.D.
PHONE NUMBER: 513-558-8440

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 1/89

2. Does your clinic perform IVF/GIFT treatments? yes -- plan to begin early January 1989
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians ______
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? just opening

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1st scan on drug 2/8/89 GIFT ______

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF ______
GIFT _____ GIFT ______

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF _______
GIFT _____ GIFT ______

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ________ 1988 ________

How many embryo transfer cycles were performed?
1987 ________ 1988 ________

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ________ 1988 _________

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ __%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ______________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF ___ 1988 IVF ___
GIFT ___ GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF ___
GIFT ___ GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF ___
GIFT ___ GIFT ___

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF ___
GIFT ___ GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ______________________
GIFT ___ ___% ______________________

1988 IVF ___ ___% ______________________
GIFT ___ ___% ______________________

21. What are the qualifications of the director of the embryo laboratory? 3 years experience in very successful IVF program (UCLA) - training (degree - M.D. 1½ yr. as director of laboratory at UCLA

22. Who supervises the laboratory director? laboratory director is the director of the program

23. Does the clinic participate in an external laboratory proficiency testing program? no
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? not as yet - just opening

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 1
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists 1
    (d) Nurses 2
    (e) Other (explain) ______

currently involved in training

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Cleveland Clinic Foundation
ADDRESS: Department of Gynecology
One Clinic Center
9500 Euclid Avenue
Cleveland, OH 44195-5037
CONTACT PERSON: Martin M. Quigley, MD
PHONE NUMBER: (216) 444-2240

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 10/15/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based ______
   (c) University based ______
   (d) Other (explain) Not for profit public foundation (multi-specialy group practice)

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   (a) Physicians 1
   (b) Laboratory Scientists (PhDs) 4
   (c) Nurses 4
   (d) Embryo Lab Technicians/Technologists 3
   (e) Other Lab Technicians/Technologists 12
   (f) Radiology (Ultrasound) Technicians 6
   (g) Psychologists/Counselors 1
   (h) Secretaries 2
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 22

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 10/84 GIFT 4/86

9. How many different patients were stimulated?
1987 IVF 130 1988 IVF 99 (15 patients had
GIFT 2 GIFT 0 stimulations in both
1987 & 1988)

10. How many stimulation cycles were performed?
1987 IVF 176 1988 IVF 141
GIFT 2 GIFT -

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 149 1988 112

How many embryo transfer cycles were performed?
1987 119 1988 97

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 2 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 141 80.1% 1988 14 9.3 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 91 51.7% 1988 IVF 75 53.2%
GIFT 0 ___% GIFT - ___%
(b) Endometriosis:
1987 IVF 65 36.9% 1988 IVF 37 26.2%
GIFT 1 50.0 % GIFT - ___%
(c) Male infertility:
1987 IVF 50 28.4% 1988 IVF 39 27.7%
GIFT 0 ___% GIFT - ___%
(d) Unexplained infertility:
1987 IVF 18 10.2% 1988 IVF 5 3.5%
GIFT 0 ___% GIFT - ___%
(e) Other (explain): cervical, immunologic, ovulatory dysfun-
1987 IVF 31 17.6% 1988 IVF 29 20.6% ction, ovarian fail-
GIFT 1 50 % GIFT - ___% ure

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 52 29.5% 1988 IVF 34 24.1%
GIFT 1 50 % GIFT - ___%
(b) 31-35:
1987 IVF 78 44.3% 1988 IVF 54 38.3%
GIFT 1 50 % GIFT - ___%
(c) 36-40:
1987 IVF 37 21.0% 1988 IVF 39 27.7%
GIFT 0 ___% GIFT - ___%

(d) 41-45:
1987 IVF 9 5.1% 1988 IVF 14 9.9%
GIFT 0 ___% GIFT - ___%

(e) >45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT - ___%

16. How many clinical pregnancies were produced?
1987 IVF 21 1988 IVF 10
GIFT 0 GIFT -

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 11 1988 IVF 10
GIFT 1 GIFT -

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF - 1988 IVF 6
GIFT - GIFT -

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 1
GIFT 0 GIFT -

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 18.% Both Twins
GIFT 0 ___% ___

1988 IVF 0 ___% ___
GIFT - ___% ___

21. What are the qualifications of the director of the embryo laboratory? PhD - 30+ years experience in gamete physiology

22. Who supervises the laboratory director? Program Director & Chairman of Research Institute

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** Yes

27. **Does the clinic train individuals in IVF or GIFT?** * ______
If the answer is yes, how many individuals in the following specialties have been trained?
    - **(a) Physicians** ______
    - **(b) Laboratory scientists (PhDs)** ______
    - **(c) Embryo laboratory technicians/technologists** ______
    - **(d) Nurses** ______
    - **(e) Other (explain)** ______

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

The Cleveland Clinic Foundation is a tertiary referral center, drawing most of its patients from the surrounding 7 states. The infertility patients treated here are, in general, older, have long-standing, and often multi-factorial infertility. Because of the nature of our patients, and the interests of our Professional Staff, there is a large proportion of male factor patients. GIFT is de-emphasized as we believe that these patients require information regarding fertilization in order to make subsequent reproductive decisions. In addition to routine IVF, we have a successful which provides oocytes donated by volunteers to women with ovarian failure.

* No formal training programs but several dozen physicians, nurses, technicians, and laboratory scientists have visited our program for short familiarization observations.

IVF/GIFT SURVEY

CLINIC NAME: BETHESDA FERTILITY CENTER
ADDRESS: 619 Oak Street, 3 South
Cincinnati, Ohio 45206
#(513) 569-6433

CONTACT PERSON: NeeOo W. Chin, M.D., Director
PHONE NUMBER: #(513) 569-6433

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ____
   - (b) Community hospital based X
   - (c) University based ____
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 3
   - (e) Other Lab Technicians/Technologists 0
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 2
   - (h) Secretaries 1
   - (i) Other (specify) 0

7. How many years has your infertility clinic been in operation? 1 ½ yrs.

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 11/2/88 Surgery GIFT 9/14/88 Surgery
(~~10/18/88 Cancelled~~) (8/~~20/88 Cancelled~~)

9. How many different patients were stimulated?
1987 IVF 6 1988 IVF 37
GIFT 11 GIFT 23

10. How many stimulation cycles were performed?
1987 IVF 7 1988 IVF 48
GIFT 15 GIFT 31

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 5 1988 41

How many embryo transfer cycles were performed?
1987 5 1988 36

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 9 1988 26

13. What were the number and percentage of patients on IRB approved research protocols?
1987 1 7 % 1988 4 7 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 6 86 % 1988 IVF 14 29 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 1 14 % 1988 IVF 21 44 %
GIFT 3 20 % GIFT 7 23 %
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 11 23 %
GIFT 3 20 % GIFT 15 48 %
(d) Unexplained infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 6 40 % GIFT 6 19 %
(e) Other (explain): Cervical, Immunological
1987 IVF 0 0 % 1988 IVF 2 4 %
GIFT 3 20 % GIFT 3 10 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 3 43 % 1988 IVF 15 31 %
GIFT 2 13 % GIFT 6 19 %
(b) 31-35:
1987 IVF 3 43 % 1988 IVF 22 46 %
GIFT 10 67 % GIFT 17 55 %
(c) 36-40:
1987 IVF 1 14 % 1988 IVF 8 17 %
GIFT 3 20 % GIFT 8 26 %

Matches cycles, not patients

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 3 6 %
GIFT 0 0 % GIFT 0 0 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 2 1988 IVF 6
GIFT 3 GIFT 4

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 1 1988 IVF 0
GIFT 2 GIFT 1 (Twins)

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 5 (1 with twins at 18 weeks)
GIFT 0 GIFT 2

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0%
GIFT 0 0 %

1988 IVF 0 0%
GIFT 1 33 % Twins

21. What are the qualifications of the director of the embryo laboratory? M.S., Ph.D., Reproductive Physiology; Post graduate training courses through AFS for continuing education

22. Who supervises the laboratory director? M.D., Director of Center

23. Does the clinic participate in an external laboratory proficiency testing program? No (None Available)
If the answer is yes, please specify which program.
0

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Has applied recently for membership.

27. Does the clinic train individuals in IVF or GIFT? Not at Present
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: MacDonald Hospital for Women IVF - ET Program
ADDRESS: 2074 Abington Road
Humphrey Building Suite 1632
Cleveland, Ohio 44106

CONTACT PERSON: Cynthia Austin, M.D.
PHONE NUMBER: (216) 844-1514

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/15/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 4

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 5

6. How many other professionals participate in your clinic?
   - (a) Physicians ______
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists ______
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) Endocrinology Fellows - 2

7. How many years has your infertility clinic been in operation? 4

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 11/84 GIFT 1/85

9. How many different patients were stimulated?
1987 IVF 26 1988 IVF 49
GIFT 0 GIFT 0

10. How many stimulation cycles were performed?
1987 IVF 44 1988 IVF 96
GIFT 0 GIFT 0

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 22 1988 50

How many embryo transfer cycles were performed?
1987 19 1988 48

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0% 1988 0 0%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 10 38.5% 1988 IVF 20 40.8%
GIFT 0 ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF 5 19.2% 1988 IVF 9 18.4%
GIFT 0 ___% GIFT 0 ___%
(c) Male infertility:
1987 IVF 1 3.9% 1988 IVF 1 2.0%
GIFT 0 ___% GIFT 0 ___%
(d) Unexplained infertility:
1987 IVF 5 19.2% 1988 IVF 10 20.4%
GIFT 0 ___% GIFT 0 ___%
(e) Other (explain): more than one factor (other than tubal)
1987 IVF 5 19.2% 1988 IVF 9 18.4%
GIFT 0 ___% GIFT 0 ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 8 30.8% 1988 IVF 14 28.6%
GIFT 0 ___% GIFT 0 ___%
(b) 31-35:
1987 IVF 11 42.3% 1988 IVF 21 42.8%
GIFT 0 ___% GIFT 0 ___%
(c) 36-40:
1987 IVF 4 15.4% 1988 IVF 7 14.3%
GIFT 0 ___% GIFT 0 ___%

(d) 41-45:
1987 IVF 3 11.5% 1988 IVF 7 14.3%
GIFT 0 ___% GIFT 0 ___%
(e) >45:
1987 IVF 0 0% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF 3 1988 IVF 6
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 2 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 5
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___% ______________________
GIFT 0 ___% ______________________

1988 IVF 0 ___% ______________________
GIFT 0 ___% ______________________

21. What are the qualifications of the director of the embryo laboratory? Bachelor of Science, 5 years experience in In Vitro Laboratory, doing Master's work in Biology

22. Who supervises the laboratory director? Cynthia Austin, M.D., Clinical Director; Wendy Golden, Ph.D., Advisory

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? application pending

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 4 (2 fellows in progress)
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 1
    (d) Nurses 0
    (e) Other (explain) 0

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Laboratory for In Vitro Fertilization and Embryo Transfer
ADDRESS: Mt. Sinai Medical Center
1 Mt. Sinai Drive
Cleveland, Ohio 44106

CONTACT PERSON: Dr. Wulf Utian/Dr. James Goldfarb
PHONE NUMBER: (216) 421-5884

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Current

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ________
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) University Affiliated Hospital

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   - (a) Physicians 2
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 0
   - (f) Radiology (Ultrasound) Technicians none directly
   - (g) Psychologists/Counselors none directly
   - (h) Secretaries 1
   - (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1987

9. How many different patients were stimulated?
1987 IVF 45 1988 IVF 39
GIFT 33 GIFT 22

10. How many stimulation cycles were performed?
1987 IVF 71 1988 IVF 59
GIFT 46 GIFT 30

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 49 1988 48

How many embryo transfer cycles were performed?
1987 42 1988 43

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 38 1988 23

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 33 73% 1988 IVF 26 66%
GIFT 0 0 % GIFT 0 ___%
(b) Endometriosis:
1987 IVF 2 4 % 1988 IVF 1 3 %
GIFT 3 9 % GIFT 1 4 %
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 12 36 % GIFT 4 18 %
(d) Unexplained infertility:
1987 IVF 2 4 % 1988 IVF 3 8 %
GIFT 13 39 % GIFT 13 59 %
(e) Other (explain): Combination male and female factors
1987 IVF 8 17% 1988 IVF 9 23%
GIFT 5 15 % GIFT 4 18 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 10 22% 1988 IVF 8 20 %
GIFT 7 21 % GIFT 5 23 %
(b) 31-35:
1987 IVF 18 40% 1988 IVF 17 43 %
GIFT 14 42 % GIFT 12 54 %
(c) 36-40:
1987 IVF 14 31% 1988 IVF 12 30 %
GIFT 11 33 % GIFT 4 18 %

Tubal factor includes some cases of endometriosis which caused tubal factor

(d) 41-45:
1987 IVF 3 6 % 1988 IVF 1 3 %
GIFT 1 3 % GIFT 1 5 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 1 3 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced? (1)
1987 IVF 6 1988 IVF 8
GIFT 6 GIFT 3

17. How many women delivered live infants from IVF/GIFT?
1987(2) IVF 4 1988(3) IVF 2
GIFT 5 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
(4)1987 IVF 0 1988(5) IVF 4
GIFT 0 GIFT 2

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 0
GIFT 1 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___ %
GIFT 1 20 % twins

1988 IVF 2 33 % twins, twins
GIFT 0 ___ %

21. What are the qualifications of the director of the embryo laboratory? Ph.D. Reproductive Physiology; Five years graduate program in early mammalian development

22. Who supervises the laboratory director? Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

1. Ultrasound documented pregnancies
2. From cycles started in 1987
3. From cycles started in 1988
4. Undelivered pregnancies from 1987 conceptions
5. Undelivered pregnancies from 1988 conceptions

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Application pending

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 22
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 4
    (d) Nurses
    (e) Other (explain)

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

COMMENTS

We were the first successful IVF program in the state of Ohio, achieving a birth in November 1983. Many of our patients have attempted IVF for several years. Therefore, many of our failed cycles involve patients who have been through the program multiple times. In 1988, for example, over 25% of our IVF cycles were patients undergoing their fourth or greater cycle. Additionally, over 20% of our patients are over 38 years old. These more difficult patients frequently fail to respond to ovulation induction and dramatically increase our "dropped cycle" rate and decrease our pregnancy rate. Our IVF program in 1987 had a particularly difficult patient population as is attested to by our 31% dropped cycle rate. Our physical facilities, especially ultrasound, are limited and therefore we have not been actively recruiting "fresh" patients.

We are therefore caught in a professional dilemma. To improve our "apparent" pregnancy rates by a more selective acceptance of patients who are inherently more fertile, or to continue to provide a service to all potential patients although the opportunity to conceive may be greatly reduced in some of these couples. These factors are currently being evaluated and will have a significant impact on our future success rate.

Our GIFT success rate is satisfactory considering that our protocol calls for all patients to try 3-9 cycles of intrauterine insemination before having the GIFT procedure. Obviously the "easier" patients conceive through intrauterine insemination, leaving the more difficult patients for GIFT.

As we look to 1989 we are anticipating continued success. We have decided to be more selective in patient acceptance. We also are expanding our ultrasound services so that we will be able to recruit "fresh" patients. With a more favorable mix of patients, we are optimistic our numbers will look even better.

In addition to our traditional IVF and GIFT programs, we offer an IVF/Surrogate host program. This program provides the opportunity for women without a functional uterus to have a child who is genetically her own. This was the world's first successful IVF/Surrogate program. The ethical issues were the subject of a public television NOVA program.

IVF/GIFT SURVEY

OHIO State University

CLINIC NAME: University Reproductive Center
ADDRESS: 1654 Upham Drive, MH-535
Columbus, Ohio 43210

CONTACT PERSON Moon H. Kim, M.D. or William G. Dodds, M.D.
PHONE NUMBER: (614) 293-8511

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Dec., 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   - (a) Physicians 6 (including fellows - 3)
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 2½
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians * 0
   - (g) Psychologists/Counselors 1 part-time
   - (h) Secretaries 3
   - (i) Other (specify) *all ultrasound scanning by physicians

7. How many years has your infertility clinic been in operation? 6 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF September, 1982 GIFT 1986

9. How many different patients were stimulated?
1987 IVF 65 1988 IVF 90
GIFT 30 GIFT 53

10. How many stimulation cycles were performed?
1987 IVF 105 1988 IVF 136
GIFT 47 GIFT 81

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 79 1988 102

How many embryo transfer cycles were performed?
1987 55 1988 73

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 35 1988 65

13. What were the number and percentage of patients on IRB approved research protocols?
1987 N/A ___ % 1988 N/A ___ %
* IVF and GIFT procedures are no longer on IRB protocol

14. What were the number and percentage of ~~patients~~ cycles treated for:
(a) Tubal factor:
1987 IVF 37 35 % 1988 IVF 72 53 %
GIFT 2 4 % GIFT 4 5 %
(b) Endometriosis:
1987 IVF 43 41 % 1988 IVF 32 23 %
GIFT 18 38 % GIFT 26 32 %
(c) Male infertility:
1987 IVF 16 15 % 1988 IVF 17 12 %
GIFT 9 19 % GIFT 14 17 %
(d) Unexplained infertility:
1987 IVF 1 1 % 1988 IVF 6 4 %
GIFT 3 8 % GIFT 12 15 %
(e) Other (explain): Cervical factor, luteal phase defect, etc.
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 3 8 % GIFT 5 6 %

15. What were the number and percentage of ~~patients~~ cycles in the following age groups:
(a) <31:
1987 IVF 34 32 % 1988 IVF 41 30 %
GIFT 13 28 % GIFT 33 41 %
(b) 31-35:
1987 IVF 40 38% 1988 IVF 72 53 %
GIFT 18 39 % GIFT 30 37 %
(c) 36-40:
1987 IVF 31 30 % 1988 IVF 23 17 %
GIFT 15 33 % GIFT 18 21 %

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 1 1 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 8 1988 IVF 8
GIFT 4 GIFT 10

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 6 1988 IVF 4
GIFT 1 GIFT 4

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 2
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 0
GIFT 0 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 25 % ______
GIFT 0 0 % ______

1988 IVF 1 12.% ______
GIFT 2 20 % ______

21. What are the qualifications of the director of the embryo laboratory? M.D. or Ph.D., at least M.S. degree with a minimum of two or more years of experience in IVF and related procedures and research.

22. Who supervises the laboratory director? Program director

23. Does the clinic participate in an external laboratory proficiency testing program? No. Internal review system is used. If the answer is yes, please specify which program.
______

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 11 (including 6 foreign fellows)
    (b) Laboratory scientists (PhDs) 1
    (c) Embryo laboratory technicians/technologists 4
    (d) Nurses 3
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The University Reproductive Center IVF program has enjoyed a consistent level of clinical pregnancy success per embryo transfer of 15% since its inception in 1982. The GIFT programs success has averaged 22% clinical pregnancy success rate since its origin 3 year's ago.

Our average patient age in both our IVF and GIFT programs is higher than most centers. Approximately 70% of our IVF/GIFT patients are 32 years of age or greater with 30% being ≥ 36 years of age. We feel this reflects that many of our patients are referred after several years of infertility evaluation and treatment by other physicians. This trend, however, is changing with more couples seeking primary evaluation by Reproductive Endocrinology-Infertility specialists.

IVF/GIFT SURVEY

CLINIC NAME: Miami Valley Hosp Fertility Program
ADDRESS:
1 Wyoming St
Dayton Ohio 45409

CONTACT PERSON: Robert C. Winslow MD
PHONE NUMBER: 513-228-1510

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 5

6. How many other professionals participate in your clinic?
   - (a) Physicians 6
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 4
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 1
   - (h) Secretaries ½ FTE
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 4

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 4-84 GIFT 4-86

9. How many different patients were stimulated?
1987 IVF 96 1988 IVF 21
GIFT 11 GIFT 28

10. How many stimulation cycles were performed?
1987 IVF 100 1988 IVF 45
GIFT 13 GIFT 54

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 69 1988 41

How many embryo transfer cycles were performed?
1987 50 1988 27

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 10 1988 40

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0% 1988 ___ 0%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 64 ___% 1988 IVF 31 ___%
GIFT 0 0% GIFT 1 ___%
(b) Endometriosis:
1987 IVF 14 ___% 1988 IVF 5 ___%
GIFT 7 ___% GIFT 8 ___%
(c) Male infertility:
1987 IVF 23 ___% 1988 IVF 10 ___%
GIFT 5 ___% GIFT 19 ___%
(d) Unexplained infertility:
1987 IVF 3 ___% 1988 IVF 0 ___%
GIFT 1 ___% GIFT 9 ___%
(e) Other (explain): ________________ Cervical Factor
1987 IVF 2 ___% 1988 IVF 1 ___% PCO
GIFT 3 ___% GIFT 19 ___% IMMUNOLOG.
OVULATORY DYS.

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 21 ___% 1988 IVF 13 ___%
GIFT 3 ___% GIFT 10 ___%
(b) 31-35:
1987 IVF 32 ___% 1988 IVF 15 ___%
GIFT 3 ___% GIFT 22 ___%
(c) 36-40:
1987 IVF 30 ___% 1988 IVF 16 ___%
GIFT 8 ___% GIFT 9 ___%

(d) 41-45:
1987 IVF 5 ___ % 1988 IVF 0 ___ %
GIFT 0 ___ % GIFT P ___ %
(e) >45:
1987 IVF 0 ___ % 1988 IVF 0 ___ %
GIFT u ___ % GIFT 1 ___ %

16. How many clinical pregnancies were produced?
1987 IVF 8 1988 IVF 5
GIFT 5 GIFT 8

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 5 1988 IVF 2
GIFT 3 GIFT 3

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 3
GIFT 0 GIFT 5

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 % ___
GIFT 0 0 % ___

1988 IVF 0 0 % ___
GIFT 0 0 % ___

21. What are the qualifications of the director of the embryo laboratory? M.D. PATHOLOGIST

22. Who supervises the laboratory director? NA

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? yes

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 0
    (b) Laboratory scientists (PhDs) 1
    (c) Embryo laboratory technicians/technologists 7
    (d) Nurses 0
    (e) Other (explain) 0

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

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Hon Ron Wyden

IVF/GIFT SURVEY

CLINIC NAME: Henry G. Bennett, Jr. Fertility Institute
ADDRESS: 3433 Northwest 56th, Suite 200
Oklahoma City, Oklahoma 73112

CONTACT PERSON: David A. Kallenberger, M.D.
PHONE NUMBER: (405)949-6060

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 9/30/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 6

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 0
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) O.R. Team

7. How many years has your infertility clinic been in operation? 2 1/2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF March, 1986 GIFT Jan., 1987

9. How many different patients were stimulated?
1987 IVF 17 1988 IVF 24
GIFT 34 GIFT 30

10. How many stimulation cycles were performed?
1987 IVF 24 1988 IVF 31
GIFT 45 GIFT 34

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 23 1988 19

How many embryo transfer cycles were performed?
1987 18 1988 13

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 30 1988 28

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 18 78% 1988 IVF 9 47%
GIFT 10 33% GIFT 8 29%
(b) Endometriosis:
1987 IVF 2 8% 1988 IVF 1 5%
GIFT 5 17% GIFT 3 11%
(c) Male infertility:
1987 IVF 0 0% 1988 IVF 3 16%
GIFT 3 10% GIFT 0 0%
(d) Unexplained infertility:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 3 10% GIFT 3 11%
(e) Other (explain): Multiple, Ovulatory Dysfunction, or Cervical Factor.
1987 IVF 3 13% 1988 IVF 6 32%
GIFT 9 30% GIFT 14 50%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 6 26% 1988 IVF 5 26%
GIFT 11 37% GIFT 6 21%
(b) 31-35:
1987 IVF 8 35% 1988 IVF 10 53%
GIFT 14 47% GIFT 12 43%
(c) 36-40:
1987 IVF 7 30% 1988 IVF 2 11%
GIFT 5 17% GIFT 9 32%

(d) 41-45:
1987 IVF 2 9% 1988 IVF 2 11%
GIFT 0 0% GIFT 1 4%

(e) >45:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 0 0%

16. How many clinical pregnancies were produced?
1987 IVF 5 1988 IVF 1
GIFT 13 GIFT 9

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 3 1988 IVF 1
GIFT 2 GIFT 6

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 5

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 2 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0% ____________________
GIFT 0 0% ____________________

1988 IVF 1 100% Twins
GIFT 1 17% Twins

21. What are the qualifications of the director of the embryo laboratory? PhD with experience in embryology, andrology and Cryobiology. Previous documented success in an IVF-GIFT program. Experienced in mouse Q.C. procedures.

22. Who supervises the laboratory director? Medical Director

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** Yes

27. **Does the clinic train individuals in IVF or GIFT?** Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    - **(a) Physicians** ________
    - **(b) Laboratory scientists (PhDs)** ________
    - **(c) Embryo laboratory technicians/technologists** 3
    - **(d) Nurses** 2
    - **(e) Other (explain)** ________

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

The overall success of the IVF/GIFT program has been directly affected by several significant factors. The number of stimulated cycles has been low due to small patient population resulting from local economic factors. The economy as well has influenced patient population age, allowing older (35-40 years), more financially secure patients to more readily participate. A third factor affecting overall success is reflected in patient indication for IVF/GIFT. Of significance are the numbers of male factor and advanced endometriosis indications in our patient population.

IVF/GIFT SURVEY

CLINIC NAME: Hillcrest Fertility Center
ADDRESS: 1145 S. Utica, Suite 1209
Tulsa, OK 74104

CONTACT PERSON: Dr. Donald R. Tredway or Dr. Stanley G. Prough
PHONE NUMBER: (918) 584-2870

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12-30-88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   - (a) Physicians ______
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 3
   - (d) Embryo Lab Technicians/Technologists ______
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors ______
   - (h) Secretaries 3
   - (i) Other (specify) Office Manager

7. How many years has your infertility clinic been in operation? 6

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 12-82 GIFT 9-86

9. How many different patients were stimulated?
1987 IVF 46 1988 IVF 52
GIFT 0 GIFT 0

10. How many stimulation cycles were performed?
1987 IVF 46 1988 IVF 52
GIFT 0 GIFT 0

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 40 1988 50

How many embryo transfer cycles were performed?
1987 39 1988 49

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 100 % 1988 ___ 100 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 25 67 % 1988 IVF 27 52 %
GIFT 0 ___ % GIFT ___ ___ %
(b) Endometriosis:
1987 IVF 4 9 % 1988 IVF 8 15 %
GIFT ___ ___ % GIFT ___ ___ %
(c) Male infertility:
1987 IVF 11 24 % 1988 IVF 9 17 %
GIFT ___ ___ % GIFT ___ ___ %
(d) Unexplained infertility:
1987 IVF 6 13 % 1988 IVF 8 15 %
GIFT ___ ___ % GIFT ___ ___ %
(e) Other (explain): ___
1987 IVF ___ ___ % 1988 IVF ___ ___ %
GIFT ___ ___ % GIFT ___ ___ %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 8 20 % 1988 IVF 16 31 %
GIFT 0 ___ % GIFT ___ ___ %
(b) 31-35:
1987 IVF 20 50 % 1988 IVF 27 52 %
GIFT 0 ___ % GIFT 0 ___ %
(c) 36-40:
1987 IVF 9 22 % 1988 IVF 7 14 %
GIFT 0 ___ % GIFT 0 ___ %

(d) 41-45:
1987 IVF 3 7 % 1988 IVF 2 4 %
GIFT 0 ___ % GIFT ___ ___ %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 ___ %
GIFT 0 ___ % GIFT ___ ___ %

16. How many clinical pregnancies were produced?
1987 IVF 3 1988 IVF 9
GIFT 0 GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 2 1988 IVF 0
GIFT 0 GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 7
GIFT 0 GIFT ___

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 3 100 % 1 triplets, 2 twins
GIFT 0 ___ % ___

1988 IVF 3 ___ % 3 twins
GIFT 0 ___ % ___

21. What are the qualifications of the director of the embryo laboratory? Ph.D. Embryologist

22. Who supervises the laboratory director? Medical Director

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
Outside consultants and Hillcrest Medical Center

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 4
    (b) Laboratory scientists (PhDs) 2
    (c) Embryo laboratory technicians/technologists 2
    (d) Nurses 3
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: The Oregon Health Sciences University
ADDRESS: L466
3181 S.W. Sam Jackson Pk. Rd
Portland, OR 97201

CONTACT PERSON: Jean Craemer RN, MPH
PHONE NUMBER: 503 - 279-8449

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the never clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? November 1988

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   - (a) Physicians 4
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 4
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 2
   - (h) Secretaries 4
   - (i) Other (specify) 1 urologist

7. How many years has your infertility clinic been in operation? 5 IVF program begun 1983

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF May, 1983 GIFT Sept 1986

9. How many different patients were stimulated?
1987 IVF 55 1988 IVF 55
GIFT 21 GIFT 23

10. How many stimulation cycles were performed?
1987 IVF 77 1988 IVF 63
GIFT 32 GIFT 28

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 49 1988 53

How many embryo transfer cycles were performed?
1987 45 1988 42

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 16 1988 18

13. What were the number and percentage of patients on IRB approved research protocols? (the cryopreservation procedure)
1987 20 26% 1988 26 33%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

DATA NOT AVAILABLE

(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ___
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 8 10.4% 1988 IVF 7 11.1%
GIFT 3 9.3% GIFT 3 10.7%
(b) 31-35:
1987 IVF 41 55.8% 1988 IVF 24 38.1%
GIFT 9 28.1% GIFT 13 46.4%
(c) 36-40:
1987 IVF 21 27.3% 1988 IVF 28 44.4%
GIFT 18 56.3% GIFT 10 35.7%

(d) 41-45:
1987 IVF 5 6.5 % 1988 IVF 4 6.4 %
GIFT 2 6.3 % GIFT 2 7.1 %

(e) >45:
1987 IVF 0 - % 1988 IVF 0 - %
GIFT 0 - % GIFT 0 - %

16. How many clinical pregnancies were produced?
1987 IVF 4 1988 IVF 6
GIFT 3 GIFT 8

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 3 1988 IVF 3
GIFT 2 GIFT 3

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 9
GIFT 0 GIFT 5
all have delivered

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 0
GIFT 0 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 33 % 1 set of twins
GIFT 1 50 % 1 set of triplets

1988 IVF 2 66 % 2 sets of twins
GIFT 2 66 % 1 set of twins & 1 set of triplets

21. What are the qualifications of the director of the embryo laboratory? Ph.D., 10 years experience in clinical IVF, 15 years in basic research on mammalian fertilization, edited 2 books on human IVF-ET

22. Who supervises the laboratory director? no one

23. Does the clinic participate in an external laboratory proficiency testing program? no
If the answer is yes, please specify which program.
we do our own quality assurance testing

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? YES

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? YES

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 3
    (b) Laboratory scientists (PhDs) 1
    (c) Embryo laboratory technicians/technologists 3
    (d) Nurses 6
    (e) Other (explain) -

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The Oregon Health Sciences University's IVF/GIFT statistics represent an unselected patient population which is not limited on the basis of age, infertility diagnosis or duration of infertility. We associate a major improvement in pregnancy rates, from 1987 to 1988 with a change in the follicular recruitment protocol employed.

This program initiated embryo cryopreservation as an experimental, Investigational Research Board (IRB) approved activity in early 1987. Pregnancies and live birth have resulted.

As a relatively small (low volume) academic program, our objectives include: (1) defining and developing state-of-the-art advances in the technology; (2) conducting IRB approved experimental protocols; and (3) participating in the accreditation of IVF support laboratories.

IVF/GIFT SURVEY

CLINIC NAME: Northwest Fertility Center
ADDRESS: Emanuel Hospital and Health Center
2801 N. Gantenbein Avenue
Portland, Oregon 97227

CONTACT PERSON: Eugene M. Stoelk, M.D.
PHONE NUMBER: (503) 280-3097

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based X
   (c) University based ______
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? One

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? None

6. How many other professionals participate in your clinic?
   (a) Physicians None
   (b) Laboratory Scientists (PhDs) None
   (c) Nurses 4
   (d) Embryo Lab Technicians/Technologists One
   (e) Other Lab Technicians/Technologists One
   (f) Radiology (Ultrasound) Technicians 4
   (g) Psychologists/Counselors None
   (h) Secretaries One
   (i) Other (specify) Business Mgr

7. How many years has your infertility clinic been in operation? 2 1/2 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF April 1987 GIFT Sept. 1987

9. How many different patients were stimulated?
1987 IVF 20 1988 IVF 40
GIFT 2 GIFT 2

10. How many stimulation cycles were performed?
1987 IVF 29 1988 IVF 66
GIFT 2 GIFT 2

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 27 1988 54

How many embryo transfer cycles were performed?
1987 25 1988 50

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 2 1988 2

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0% 1988 0 0%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 17 85% 1988 IVF 33 82%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 2 10% 1988 IVF 4 10%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF 1 5% 1988 IVF 2 5%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF 1 5% 1988 IVF 5 13%
GIFT 2 100% GIFT 2 100%
(e) Other (explain): Age - Donor oocytes
1987 IVF ___ ___% 1988 IVF 1 2.5%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 5 25% 1988 IVF 11 27.5%
GIFT ___ ___% GIFT 1 50%
(b) 31-35:
1987 IVF 11 55% 1988 IVF 18 45%
GIFT 1 50% GIFT 1 50%
(c) 36-40:
1987 IVF 4 20% 1988 IVF 11 27.5%
GIFT 1 50% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 4 1988 IVF 8
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 4 1988 IVF 2
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF N.A. 1988 IVF 4
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0%
GIFT 0 0%

1988 IVF 1 17% twins (1 set)
GIFT 0 0%

21. What are the qualifications of the director of the embryo laboratory? M.S. plus 5 years experience directing human IVF embryo lab

22. Who supervises the laboratory director? Medical Director

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
Mouse embryo control testing

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Applied for

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Fertility Center at ST. Luke's
ADDRESS: ~~[illegible]~~
821 Ostrum St.
Bethlehem PA 18015

CONTACT PERSON: Judy Dean
PHONE NUMBER: 215- 8 691- 4825

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12-15-88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   - (a) Physicians ______
   - (b) Laboratory Scientists (PhDs) ______
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors 1
   - (h) Secretaries ______
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1987 GIFT 1986

9, How many different patients were stimulated?
See #28
1987 IVF X 1988 IVF 7
GIFT X GIFT 59

10, How many stimulation cycles were performed?
See #28
1987 IVF X 1988 IVF 10
GIFT X GIFT 99

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 6 1988 10

How many embryo transfer cycles were performed?
1987 5 1988 8

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 59 1988 52

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 4 57% 1988 IVF 1 10%
GIFT 10 17 % GIFT 7 14%
(b) Endometriosis:
1987 IVF 1 14% 1988 IVF 1 10%
GIFT 24 41 % GIFT 18 35%
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 1 10%
GIFT 4 7 % GIFT 12 23 %
(d) Unexplained infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 4 7 % GIFT 3 6 %
(e) Other (explain): Pelvic Adhesions + uterine myomas
1987 IVF 2 29% 1988 IVF 1 10%
GIFT 17 28% GIFT 11 22%

15. What were the number and percentage of patients in the following age groups:
See #28
(a) <31:
1987 IVF 5 84% 1988 IVF 5 50%
GIFT 26 44 % GIFT 22 42 %
(b) 31-35:
1987 IVF 1 16 % 1988 IVF 4 40%
GIFT 25 42 % GIFT 22 42 %
(c) 36-40:
1987 IVF 0 0 % 1988 IVF 1 10%
GIFT 7 12 % GIFT 9 16 %

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 1 2 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 1 1988 IVF 0
GIFT 8 GIFT 12

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 3 GIFT 6

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF NA 1988 IVF 0
GIFT NA GIFT 5

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 % N.A.
GIFT 2 66 % Twins

1988 IVF 0 0 % N.A.
GIFT 1 17 % Twins

21. What are the qualifications of the director of the embryo laboratory? 1 yr. work in non-human mammalian IVF (U. of WA.), 4 mos. training in Human IVF (Swedish Med. Ctr. - Seattle, WA.), IVF Lab Director - 4 yrs. - (AZ. FERT. INST. - Phoenix, AZ) IVF/GIFT LAB DIRECTOR - 1 yr (St Luke's Hosp. - Bethlehem, PA)

22. Who supervises the laboratory director? Dr. F. [illegible]

23. Does the clinic participate in an external laboratory proficiency testing program? yes
If the answer is yes, please specify which program.
CAP for osmolalities only.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? NO

27. Does the clinic train individuals in IVF or GIFT? NO
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ______
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ______
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

TO WHOM IT MAY CONCERN: PRIOR TO NOVEMBER 1987, PATIENTS STIMULATED, BUT NOT TAKEN TO SURGERY WERE NOT BEING INCLUDED IN DATA COLLECTION (THUS THEY HAD BEEN PURGED FROM THE SYSTEM). AFTER MY ARRIVAL AS NEW LAB DIRECTOR (11/87) WE BEGAN TO RECORD THIS DATA AS WELL. CONSEQUENTLY QUESTIONS #'S 9 & 10 ARE NOT COMPLETED FOR 1987 ONLY. LIKEWISE QUESTION #15 REPRESENTS AGE DISTRIBUTION ONLY FOR PATIENT'S TO SURGERY IN 1987. ALL DATA FOR 1988 IS COMPLETE AND CURRENT FOR THE ENTIRE YEAR WITH THE EXCEPTION OF ONE PREGNANCY TEST RESULT WHICH IS STILL PENDING. IF I MAY BE OF ANY FURTHER ASSISTANCE DO NOT HESITATE TO CALL

STEPHEN P. PAZDZIORKO
LAB DIRECTOR
(215) 691-7323

IVF/GIFT SURVEY

CLINIC NAME: CHRISTIAN FERTILITY INSTITUTE
ADDRESS: 241 NORTH 13th STREET
EASTON, PA 18042

CONTACT PERSON: WILLIAM ISAAC COOPER, M.D.
PHONE NUMBER: 215 250-9700

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ✓
   (b) Community hospital based ______
   (c) University based ______
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 0

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   (a) Physicians 2
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 3
   (d) Embryo Lab Technicians/Technologists 1
   (e) Other Lab Technicians/Technologists 1
   (f) Radiology (Ultrasound) Technicians 0
   (g) Psychologists/Counselors 0
   (h) Secretaries 1
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 3

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1986- GIFT N/A

9. How many different patients were stimulated?
1987 IVF 59 1988 IVF 75
GIFT N/A GIFT N/A

10. How many stimulation cycles were performed?
1987 IVF 90 1988 IVF 107
GIFT N/A GIFT N/A

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 90 1988 106

How many embryo transfer cycles were performed?
1987 71 1988 83

12. How many GIFT procedures (attempted egg recoveries) were performed? N/A
1987 — 1988 —

13. What were the number and percentage of patients on IRB approved research protocols? NONE
1987 — —% 1988 — —%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 35 59% 1988 IVF 43 57%
GIFT N/A ___% GIFT N/A ___%
(b) Endometriosis:
1987 IVF 9 15% 1988 IVF 10 13%
GIFT N/A ___% GIFT N/A ___%
(c) Male infertility:
1987 IVF 10 17% 1988 IVF 21 28%
GIFT N/A ___% GIFT N/A ___%
(d) Unexplained infertility:
1987 IVF 5 8.5% 1988 IVF 8 10.5%
GIFT N/A ___% GIFT N/A ___%
(e) Other (explain): ____________
1987 IVF 0 0% 1988 IVF 0 0%
GIFT N/A ___% GIFT N/A ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 12 20% 1988 IVF 15 20%
GIFT N/A ___% GIFT N/A ___%
(b) 31-35:
1987 IVF 24 40.5% 1988 IVF 32 42.5%
GIFT N/A ___% GIFT N/A ___%
(c) 36-40:
1987 IVF 18 30.5% 1988 IVF 25 33%
GIFT N/A ___% GIFT N/A ___%

(d) 41-45:
1987 IVF 0 0% 1988 IVF 3 4%
GIFT N/A ___% GIFT N/A ___%

(e) >45:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT N/A ___% GIFT N/A ___%

16. How many clinical pregnancies were produced?
1987 IVF 15 1988 IVF 19
GIFT N/A GIFT N/A

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 5 1988 IVF 14
GIFT N/A GIFT N/A

18. How many women have continuing pregnancies from IVF/GIFT?
from 1987 into 1988 IVF 8 GIFT N/A
fr 1988 into 1989 IVF 8 GIFT N/A

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT N/A GIFT N/A

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 40% all twin ~~gestation~~ births
GIFT N/A ___% ______

1988 IVF 5 35.9% all twin ~~gestations~~ births
GIFT N/A ___% ______

21. What are the qualifications of the director of the embryo laboratory? Ph.D in Developmental Biology, with emphasis on IVF, 1986, Univ. of London
CERTIFIED FULLY TRAINED IN ALL ASPECTS OF IVF-ET AT [redacted] HALLEM MEDICAL CENTRE, LONDON, ENGLAND
ALSO TRAINING AT KING'S COLLEGE HOSPITAL, OXFORD UNIV., LONDON, ENGLAND

22. Who supervises the laboratory director? M.D. (QUESTION #5)

23. Does the clinic participate in an external laboratory proficiency testing program? YES
If the answer is yes, please specify which program.
CERTIFIED LABORATORY - PENNSYLVANIA STATE DEPT. OF HEALTH BUREAU OF QUALITY ASSURANCE

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? [redacted] NO

26. Is the clinic a member of the Society for Assisted Reproductive Technology? ____YES________

27. *Does the clinic train* individuals in IVF or GIFT? __NO__
If the answer is yes, how many individuals in the following specialties have been trained?
   (a) Physicians ______
   (b) Laboratory scientists (PhDs) ______
   (c) Embryo laboratory technicians/technologists _____
   (d) Nurses ______
   (e) Other (explain) _______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Albert Einstein Medical Center, Northern Division
ADDRESS: Dept OB/GYN
Klein POB-400
York + Tabor Rds
Phila, PA 19141
CONTACT PERSON: Erlynne Gill Haberman, RN, MSN
PHONE NUMBER: 215-456-7990

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/30/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 0

6. How many other professionals participate in your clinic?
   - (a) Physicians 1
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 3
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 3 (2-part-time basis)
   - (h) Secretaries 3
   - (i) Other (specify) Financial Counsellor- 1

7. How many years has your infertility clinic been in operation? 3 3/4 yrs.

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1/85 GIFT 5/87

9. How many different patients were stimulated?
1987 IVF [illegible] 38 1988 IVF 50
GIFT 2 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 45 1988 IVF 67
GIFT 2 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 38 1988 57

How many embryo transfer cycles were performed?
1987 27 1988 46

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 2 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0 % 1988 ___ 8 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 25 66 % 1988 IVF 30 60 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 6 16 % 1988 IVF 12 24 %
GIFT [illegible] 50 % GIFT 0 0 %
(c) Male infertility:
1987 IVF 4 10 % 1988 IVF 3 6 %
GIFT 0 0 % GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 2 5 % 1988 IVF 3 6 %
GIFT 1 50 % GIFT 0 0 %
(e) Other (explain): Anovulation
1987 IVF 1 2.5 % 1988 IVF ___ 4 %
GIFT ___ ___ % GIFT 1 100 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 13 34 % 1988 IVF 11 22 %
GIFT ___ ___ % GIFT 1 100 %
(b) 31-35:
1987 IVF 14 37 % 1988 IVF 21 42 %
GIFT 1 50 % GIFT ___ ___ %
(c) 36-40:
1987 IVF 11 29 % 1988 IVF 17 34 %
GIFT 1 50 % GIFT ___ ___ %

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 1 2 %
GIFT ___ ___ % GIFT ___ ___ %
(e) >45:
1987 IVF 0 0 % 1988 IVF ___ ___ %
GIFT ___ ___ % GIFT ___ ___ %

16. How many clinical pregnancies were produced?
1987 IVF 7 1988 IVF 5
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 6 1988 IVF 3
GIFT 0 GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 3
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 33 % Twins
GIFT 0 ___ % ___

1988 IVF 0 ___ % ___
GIFT 0 ___ % ___

21. What are the qualifications of the director of the embryo laboratory? PhD with Specialization in embryology

22. Who supervises the laboratory director? Chairman of Dept. OB/Gyn

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program. ___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Has applied for membership 10/88.

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 1
    (b) Laboratory scientists (PhDs) ____
    (c) Embryo laboratory technicians/technologists 3
    (d) Nurses ____
    (e) Other (explain) ____

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Hospital of the University of Pennsylvania
ADDRESS: One Dulles Building
3400 Spruce Street
Philadelphia, PA 19104
CONTACT PERSON: Richard W. Tureck, M.D.
PHONE NUMBER: (215)662-6560

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year, and where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ____
   - (b) Community hospital based ____
   - (c) University based X
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 6

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 6

6. How many other professionals participate in your clinic?
   - (a) Physicians --
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 4
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists --
   - (f) Radiology (Ultrasound) Technicians --
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) 1 financial counselor

7. How many years has your infertility clinic been in operation? 6

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 5/82 GIFT 10/85

9. How many different patients were stimulated?
1987 IVF 152 — 1988 IVF 196
GIFT 18 — GIFT 32

10. How many stimulation cycles were performed?
1987 IVF 228 — 1988 IVF 310
GIFT 18 — GIFT 32

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 186 — 1988 264

How many embryo transfer cycles were performed?
1987 151 — 1988 226

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 16 — 1988 27

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0 % — 1988 3 .5%

14. What were the number and percentage of patients treated for:

(a) Tubal factor:
1987 IVF ___ 40-50% — 1988 IVF ___ 40-50%
GIFT ___ 0 % — GIFT ___ 0 %

(b) Endometriosis:
1987 IVF ___ 20-30% — 1988 IVF ___ 20-30%
GIFT ___ ___% — GIFT ___ ___%

(c) Male infertility:
1987 IVF ___ 10% — 1988 IVF 17 6 %
GIFT ___ ___% — GIFT ___ ___%

(d) Unexplained infertility:
1987 IVF ___ 10% — 1988 IVF ___ 10%
GIFT ___ ___% — GIFT ___ ___%

(e) Other (explain): Immunological infertility
1987 IVF ___ 10% — 1988 IVF ___ 10%
GIFT ___ ___% — GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:

(a) <31:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(b) 31-35:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(c) 36-40:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF 15 10% 1988 IVF 60 25%
GIFT ___ ___% GIFT 3 10%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 25 1988 IVF 43
GIFT 2 GIFT 2

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 19 1988 IVF 14
GIFT 0 GIFT 3

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 24
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 3 17% 3 sets of twins
GIFT 1 100% 1 set of twins

1988 IVF 2 10% 2 sets of twins/3 ongoing twins
GIFT 0 0% ___

21. What are the qualifications of the director of the embryo laboratory? V.M.D., Ph.D., 25 years experience as reproductive scientist - three years as lab director IVF LABORATORY.

22. Who supervises the laboratory director? Laboratory director and physicians confer daily at organized meeting to review patient progress and establish protocols.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 6
    (b) Laboratory scientists (PhDs) 1
    (c) Embryo laboratory technicians/technologists 2
    (d) Nurses 4
    (e) Other (explain)

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The patient population at the Hospital of the University of Pennsylvania consists of patients referred on a national-international basis as well as patients in the immediate vicinity of the Hospital. All patients have undergone a complete evaluation for infertility and have undertaken treatment by IVF-ET for a disease of the reproductive tract not amenable to the usual surgical-medical modalities. The success rate in 1988 for patients under the age of 40 with no accompanying male factor was 21.6% of patients per embryo transfer.

IVF/GIFT SURVEY

CLINIC NAME: Pittsburgh Institute of Reproductive Medicine
ADDRESS: 510 S. Aiken Avenue
Suite 312
Pittsburgh,PA 15232

CONTACT PERSON: Amir H. Ansari, M.D.
PHONE NUMBER: (412) 622-1720

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 1/10/89

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University ~~based~~ Affiliated - Medical College of PA (Western Division)
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? One

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   - (a) Physicians 3
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists ______
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 2
   - (i) Other (specify) 24 hr. In-house Endocrine Laboratory

7. How many years has your infertility clinic been in operation? 2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 9/22/87 GIFT 3/27/88

9. How many different patients were stimulated?
1987 IVF 5 1988 IVF 10
GIFT 0 GIFT 8

10. How many stimulation cycles were performed?
1987 IVF 5 1988 IVF 12
GIFT 0 GIFT 8

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 5 1988 10

How many embryo transfer cycles were performed?
1987 3 1988 9

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 8

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 3 60 % 1988 IVF 6 60 %
GIFT 0 0 % GIFT 1 12.5 %
(b) Endometriosis:
1987 IVF 1 20 % 1988 IVF 3 30 %
GIFT 0 0 % GIFT 6 ___ %
(c) Male infertility:
1987 IVF ___ ___ % 1988 IVF 1 10 %
GIFT ___ ___ % GIFT 1 12.5 %
(d) Unexplained infertility:
1987 IVF 1 20 % 1988 IVF ___ ___ %
GIFT ___ ___ % GIFT ___ ___ %
(e) Other (explain): ___
1987 IVF ___ ___ % 1988 IVF ___ ___ %
GIFT ___ ___ % GIFT ___ ___ %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 1 20 % 1988 IVF 3 20 %
GIFT ___ ___ % GIFT 2 25 %
(b) 31-35:
1987 IVF 3 60 % 1988 IVF 5 50 %
GIFT ___ ___ % GIFT 4 50 %
(c) 36-40:
1987 IVF 1 20 % 1988 IVF 1 10 %
GIFT ___ ___ % GIFT 2 25 %

(d) 41-45:
1987 IVF ___ ___% 1988 IVF 1 10%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 2 1988 IVF 2
GIFT ___ GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT ___ GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 2 (1-due March 6, 1988 Twin)
GIFT ___ GIFT ___ 1-due

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT ___ GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ___
GIFT ___ ___% ___

1988 IVF ___ ___% ___
GIFT ___ ___% ___

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Reproductive Physiology with 4 years of previous experience in a successful IVF Program elsewhere.

22. Who supervises the laboratory director? Amir H. Ansari, M.D.
Institute Director

23. Does the clinic participate in an external laboratory proficiency testing program? No.
If the answer is yes, please specify which program.
Internal monitoring mouse embryo assays.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No.

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Application in file

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists 2
    (d) Nurses ________
    (e) Other (explain) Physician Assistant x2

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Institute Director has had 2 years of fellowship training in general and gynecologic endocrinology as well as one year of training in infertility. Director has ample training and experience in all aspects of infertility and has worked in the IVF field both in human and monkey since 1982. Laboratory Director has had excellent training in reproductive biology and established a very successful IVF laboratory with several successful pregnancies at Rush Presbyterian Medical Center in Chicato. Presently we are engaged in a new ovulation protocal Lupron & gonadatropic hormone and are very successful in egg retrieval per vagina under sedation. Our success with egg recovery is more than 90% and fertilization of 85%. In a relatively short period of time we have had 4 pregnancies (proven by ultrasound) two of which are ongoing successful pregnancies.

Recently we have implemented embryo freezing in our program and presently have extra embryos in our freezing unit for the last two patients.

IVF/GIFT SURVEY

CLINIC NAME: Endocrine Histology Associates, P.C.
ADDRESS: 7447 Old York Road
Melrose Park, PA 19126

CONTACT PERSON: Khosrow Nowroozi, M.D. or Jerome Check, M.D.
PHONE NUMBER: (215) 635-5518

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? December 5, 1988

2. Does your clinic perform IVF/GIFT treatments? Yes, only IVF
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    - (a) Private X
    - (b) Community hospital based ________
    - (c) University based ________
    - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1 *see #28

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
    - (a) Physicians 5
    - (b) Laboratory Scientists (PhDs) 0
    - (c) Nurses 4
    - (d) Embryo Lab Technicians/Technologists 3
    - (e) Other Lab Technicians/Technologists 9
    - (f) Radiology (Ultrasound) Technicians 5
    - (g) Psychologists/Counselors 0
    - (h) Secretaries 3
    - (i) Other (specify) 1 physician's assistant

7. How many years has your infertility clinic been in operation? 12 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF January, 1988 GIFT not done

542-118
from zigur weyland

- 2 -

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF 129
GIFT ______ GIFT ______

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF 211
GIFT ______ GIFT ______

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ________ 1988 200

How many embryo transfer cycles were performed?
1987 ________ 1988 155

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ________ 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF 63 48.9%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 3 2.3 %
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 31 24.0 %
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF 29 22.5 %
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): premature ovarian failure (donor oocytes used)
1987 IVF ___ ___% 1988 IVF 3 2.3%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF 32 24.8 %
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF 55 42.6 %
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF 33 25.6 %
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF 9 7.0%
GIFT ___ ___% GIFT ___ ___%
(e) >45:
1987 IVF ___ ___% 1988 IVF 0 0%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF ___ 1988 IVF 24 through December 5, 1988
GIFT ___ GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF 1 through December 5, 1988
GIFT ___ GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 16 NOTE: A 17th pregnancy was terminated due to Down's Syndrome not related to the IVF procedure.
GIFT ___ GIFT ___

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF 1
GIFT ___ GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ___
GIFT ___ ___% ___

1988 IVF ___ ___% no multiple births
GIFT ___ ___% ___

21. What are the qualifications of the director of the embryo laboratory? Master of Science plus 5 years of embryology experience.

22. Who supervises the laboratory director? Jerome Check, M.D. and Khosrow Nowroozi, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program. ___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes *see #28

26. Is the clinic a member of the Society for Assisted Reproductive Technology? applying for membership

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
(a) Physicians ________
(b) Laboratory scientists (PhDs) _______
(c) Embryo laboratory technicians/technologists _____
(d) Nurses _______
(e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Due to our low fee schedule patients who have a small number of follicles in a given cycle often choose to complete their cycle. Even with marked sperm abnormalities, patients are willing to try one cycle of IVF, before considering donor sperm.

Because of our comprehensive investigation of multiple cycles using PEP levels, endometrial biopsies and hmg therapy before attempting IVF, we feel confident with our diagnosis of unexplained infertility. We attempt to determine these are truly unexplained infertility and are not pregnancies achieved by hmg alone without the need for IVF.

As noted, we also do not reject patients because of age and because of work we have been doing related to older patients we tend to attract an older clientel.

The two co-supervisors, Jerome H. Check, M.D., and Khosrow Nowroozi, M.D., have completed fellowships in Reproductive Endocrinology. Dr. Check is board certified in Endocrinology and Metabolism. Negotiations are close to completion of have Dr. Chung Wu, M.D.,as the additional supervisor and he is board certified in Reproductive Endocrinology.

IVF/GIFT SURVEY

CLINIC NAME: Pennsylvania Reproductive Associates at Pennsylvania Hospital
ADDRESS: 829 Spruce Street
Phila., Penna. 19107

CONTACT PERSON: Stephen L. Corson, M.D., Director
PHONE NUMBER: (215)829-5095

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private xxx
   (b) Community hospital based xxx
   (c) University based ______
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? Six (6)

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? As above only

6. How many other professionals participate in your clinic?
   (a) Physicians 1
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 6
   (d) Embryo Lab Technicians/Technologists 4
   (e) Other Lab Technicians/Technologists ______
   (f) Radiology (Ultrasound) Technicians 2
   (g) Psychologists/Counselors 2
   (h) Secretaries 3
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF Sept. 1983 GIFT April 1985

9. How many different patients were stimulated?
1987 IVF 213 1988 IVF 283
GIFT 124 GIFT 127

10. How many stimulation cycles were performed?
1987 IVF 354 1988 IVF 479
GIFT 166 GIFT 162

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 281 1988 369

How many embryo transfer cycles were performed?
1987 221 1988 298

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 130 1988 120

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 70 17 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 144 68 % 1988 IVF 150 53 %
GIFT 2 2 % GIFT 1 1 %
(b) Endometriosis:
1987 IVF 17 8 % 1988 IVF 41 14 %
GIFT 24 19 % GIFT 31 24 %
(c) Male infertility:
Corrected 1/24 MB
1987 IVF 34 16 % 1988 IVF 61 22 %
GIFT 50 40 % GIFT 51 40 %
(d) Unexplained infertility:
1987 IVF 11 5 % 1988 IVF 15 5 %
GIFT 34 27 % GIFT 25 20 %
(e) Other (explain): DES, IMMUNOLOGIC, CERVICAL
1987 IVF 7 3 % 1988 IVF 16 6 %
GIFT 14 11 % GIFT 19 15 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 48 23 % 1988 IVF 69 24 %
GIFT 17 14 % GIFT 18 14 %
(b) 31-35:
1987 IVF 100 47 % 1988 IVF 131 46 %
GIFT 61 49 % GIFT 61 48 %
(c) 36-40:
1987 IVF 58 27 % 1988 IVF 72 25 %
GIFT 37 30 % GIFT 40 31 %

(d) 41-45:
1987 IVF 16 3 % 1988 IVF 11 4 %
GIFT 9 7 % GIFT 8 6 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 39 1988 IVF 60
GIFT 34 GIFT 44

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 31 1988 IVF 12
GIFT 29 GIFT 8

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 33
GIFT 0 GIFT 25

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 2
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 7 23 % 5 TWINS, 2 TRIPLETS
GIFT 3 10 % 3 TWINS

1988 IVF 2 17 % 2 TWINS
GIFT 5 63 % 5 TWINS

21. What are the qualifications of the director of the embryo laboratory? Ph.D. MOLECULAR BIOLOGY

22. Who supervises the laboratory director? Stephen L. Corson, M.D.
Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? YES

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 15
    (b) Laboratory scientists (PhDs) 3
    (c) Embryo laboratory technicians/technologists 9
    (d) Nurses 6
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The IVF pregnancy rate per transfer for 1987 was 18% of 221 and 20% of 298 cycles of transfers in 1988. Comparable statistics for GIFT were 26% of 130 procedures in 1987 and 38% of 120 cycles in 1988. These results reflect our tendency to treat the most severe cases of reduced seminal quality with IVF so that sperm-egg interaction can be controlled and monitored in the laboratory. Even if fertilization occurs, the number of embryos replaced may be less than if normal sperm function existed, hence one expects a somewhat reduced pregnancy yield since 22% of all IVF couples we treated in 1988 had male infertility as the primary diagnosis. The pregnancy rate, for instance, for pure tubal disease is close to 26%. On the other hand, a GIFT pregnancy yield of 38% for endometriosis, mild seminal problems, and unexplained infertility is appreciably greater than that achieved with IVF. The drawback, of course, is that GIFT is a more invasive procedure as currently practiced. Twinning rates for IVF seem to be greater than that seen for GIFT (1987 Statistics) but through the years they have been equal, about 16% IN our program.

IVF/GIFT SURVEY

CLINIC NAME: Women's Clinic, LTd.
ADDRESS: 301 South Seventh Avenue - Suite 240
West Reading, PA 19611

CONTACT PERSON: Mr. David L. O'Donnell
PHONE NUMBER: (215 378-1348
215-374-2214

Reading Hosp.
&
Med. Center
Dr. Vincent Pellegrini
Dr. Jeffrey Frank

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/2/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ______
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified Medical ~~OB/or Board Eligible Reproductive~~ Endocrinologists participate in your clinic? 1 (See Note #28)

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   - (a) Physicians 4
   - (b) Laboratory Scientists ~~(PhDs)~~ 1 (See #21)
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 3
   - (i) Other (specify) 1 - Administrator

7. How many years has your infertility clinic been in operation? 8 Years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF November 1986 GIFT N/A

9. How many different patients were stimulated?
1987 IVF 31 1988 IVF 46
GIFT 0 GIFT 0

10. How many stimulation cycles were performed?
1987 IVF 45 1988 IVF 69
GIFT 0 GIFT 0

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 36 1988 60

How many embryo transfer cycles were performed?
1987 31 1988 56

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 100% 1988 ___ 100 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 19 42 % 1988 IVF 20 29%
GIFT ___ 0 % GIFT ___ 0 %
(b) Endometriosis:
1987 IVF 9 21 % 1988 IVF 18 26 %
GIFT ___ 0 % GIFT ___ 0 %
(c) Male infertility:
1987 IVF 10 22 % 1988 IVF 15 22 %
GIFT ___ 0 % GIFT ___ 0 %
(d) Unexplained infertility:
1987 IVF 1 2 % 1988 IVF 1 1 %
GIFT ___ 0 % GIFT ___ 0 %
(e) Other (explain): PCOD Immunological, CL Defect, Ovulatory Dysfunctions Kartaginer's Syndrome
1987 IVF 6 13 % 1988 IVF 15 22 %
GIFT ___ 0 % GIFT ___ 0 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 15 33 % 1988 IVF 19 27 %
GIFT ___ 0 % GIFT ___ 0 %
(b) 31-35:
1987 IVF 17 38 % 1988 IVF 29 42 %
GIFT ___ 0 % GIFT ___ 0 %
(c) 36-40:
1987 IVF 13 29 % 1988 IVF 20 29 %
GIFT ___ 0 % GIFT ___ 0 %

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT ___ 0 % GIFT ___ 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 1 1 %
GIFT ___ 0 % GIFT ___ 0 %

16. How many clinical pregnancies were produced?
1987 IVF 7 1988 IVF 10
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 5 1988 IVF 3 (See Note #28.5)
GIFT 0 GIFT 0
(Based on Cycle Initiated dates)

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 4
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 40 % 2 Sets of Twins (See Note #28.5)
GIFT ___ 0 % ______

1988 IVF 0 0 % (Based on cycle initiated dates)
GIFT ___ 0 % ______

21. What are the qualifications of the director of the embryo laboratory? B.A. Biology, Post Graduate Student at Villanova University, (5 Years), Reproductive Medicine Laboratory Experience at Eastern Virginia Medical School (2 Years), George Washington University (1 Year), Fertility Medical Laboratory (2 Years)

22. Who supervises the laboratory director? Sheldon Schlaff, M.D. and Vincent A. Pellegrini, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
College of American Pathologists Survey

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?

- **(a) Physicians** 5
- **(b) Laboratory scientists (PhDs)** 0
- **(c) Embryo laboratory technicians/technologists** 1
- **(d) Nurses** 1
- **(e) Other (explain)** ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

1. Our ultrasound confirmed clinical pregnancy per embryo transfer is 20%.
2. Ultrasound guided transvaginal aspiration is used almost exclusively for oocyte pickup (OPU) at the Women's Clinic, Ltd..
3. Our IVF Program has engaged a medical endocrinologist, Sheldon Schlaffm, M.D., as a consultant. We interact frequently on the endocrine management o four patients.
4. We define a "clinical pregnancy" as an ultrasound confirmed fetal sac, not a positive BHCG.
5. All live births in our program have occurred in 1988, but the statistics completed in questions #17 and #20 are accurate when based upon a cycle initiated date. Therefore, if #17 and #20 require delivery date;

#17 Births

	1987	1988
IVF	0	8

#20 Births

	1987	1988
IVF	0	2

Note: If a take home baby rate is to be accurately determined, these questions must be based upon cycle initiation dates.

IVF/GIFT SURVEY

CLINIC NAME: Program for In Vitro Fertilization and Embryo Transfer (PIVOT)
ADDRESS: Magee-Womens Hospital, Department of Obstetrics and Gynecology
Pittsburgh, PA 15213

CONTACT PERSON: Margie Phillips
PHONE NUMBER: (412)647-1670

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? December 1988

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based xxx
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3 - same as above

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 5
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 10
   - (g) Psychologists/Counselors 2
   - (h) Secretaries 2
   - (i) Other (specify) 2 (computer programmer, administrator)

7. How many years has your infertility clinic been in operation? 20 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1987

9. How many different patients were stimulated?
1987 IVF 27 1988 IVF 100
GIFT 42 GIFT 76

10. How many stimulation cycles were performed?
1987 IVF 50 1988 IVF 139
GIFT 62 GIFT 108

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 32 1988 100

How many embryo transfer cycles were performed?
1987 25 1988 79

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 40 1988 69

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 100 % 1988 ___ 100 % ***

**** 14. What were the number and percentage of patients treated for:
(a) Tubal factor: Percentages given are approximate:
1987 IVF ___ 80 % 1988 IVF ___ 90%
GIFT ___ 0 % GIFT ___ 0 %
(b) Endometriosis:
1987 IVF ___ 20 % 1988 IVF ___ 20 %
GIFT ___ 30 % GIFT ___ 35 %
(c) Male infertility:
1987 IVF ___ 25 % 1988 IVF ___ 15 %
GIFT ___ 0 % GIFT ___ 0 %
(d) Unexplained infertility:
1987 IVF ___ 10 % 1988 IVF ___ 10 %
GIFT ___ 75 % GIFT ___ 75 %
(e) Other (explain): see note ****
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ 10 % 1988 IVF ___ 10%
GIFT ___ 10 % GIFT ___ 10 %
(b) 31-35:
1987 IVF ___ 30 % 1988 IVF ___ 30%
GIFT ___ 30 % GIFT ___ 30 %
(c) 36-40:
1987 IVF ___ 55 % 1988 IVF ___ 55 %
GIFT ___ 55 % GIFT ___ 55 %

***Our consents for both IVF and GIFT programs have all been reviewed by IRB and as such are under IRB control.

****The exact percentages that you require are impossible to determine since we initiated over 350 cycles in the years 1987-1988. At the present time this information is being entered into a computer and we will be able to provide more accurate information in early 1989.

(d) 41-45:
1987 IVF ___ <5 % 1988 IVF ___ <5 %
GIFT ___ <5 % GIFT ___ <5 %

(e) >45:
1987 IVF ___ 0 % 1988 IVF ___ 0 %
GIFT ___ 0 % GIFT ___ 0 %

16. How many clinical pregnancies were produced?
1987 IVF 4 1988 IVF 16
GIFT 9 GIFT 30

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF 3+ one pregnancy IVF/GIFT combinati
GIFT ___ GIFT 8+ - 2 sets of twins

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 12 - 1 set of twins
GIFT ___ GIFT 21 - 1 set of twins

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 3

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 - ___ % ___
GIFT 0 ___ % ___

1988 IVF 0 ___ % ___
GIFT 3 40 % 3 sets of twins

21. What are the qualifications of the director of the embryo laboratory? Anthony J. Zeleznik, Ph.D., (see attached CV)

22. Who supervises the laboratory director? See note.

23. Does the clinic participate in an external laboratory proficiency testing program? no
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? ___ no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** yes

27. **Does the clinic train individuals in IVF or GIFT?** no
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians _______
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) _______

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

Although our program was established in 1982, it underwent reorganization in 1986 and subsequently has experienced consistent pregnancy rates in both in vitro fertilization and GIFT. All egg retrievals for IVF are performed by the transvaginal sonar-guided needle technique. In 1988, the procedure ZIFT (zygote intrafallopian transfer) was introduced. The main indication for this procedure is either male factor in the presence of a spouse with normal patent fallopian tubes or a failed GIFT cycle.

Our program undergoes an annual inspection of all techniques and procedures by an outside observer.

The exact percentages that you require are impossible to determine since we initiated over 350 cycles in the years 1987-1988. At the present time, this information is being entered into a computer and we will be able to provide more accurate information in early 1989. This will be sent to you when completed.

Addition to #14:

Percentages given are approximate: 1987 - tubal factor (IVF); 1988 - 90%. Between the years 1987-88, the procedure, ZIFT (zygote intrafallopian transfer) was introduced. At that point, patients with a known male factor were offered ZIFT rather than IVF in cases where the woman had patent fallopian tubes and there was a definite male factor.

(e) Ten percent of our IVF cycles follow unsuccessful GIFT cycles. In this situation, a couple would ahve gone through a GIFT cycle and failed to achieve a pregnancy and have been offered the option of undergoing an IVF cycle to determine whether or not there was a problem with fertilization between the ova and sperm.

Addition to #21:

Anthony J. Zeleznik, Ph.D.

Ph.D. - University of Michigan, Ann Arbor, MI
Postdoctoral Training - National Institutes of Health, Bethesda, MD, 1975-1978
Embryology Training - Institure of Obstetrics and Gynecology, University of London, Hammersmith Hospital, London, England, 1984

#24:

The following tests are performed by Magee-Womens Hospital laboratory which is accredited
by ge of American Pathologists (CAP) and participates in Proficiency Testing Program
D' nd/or American Society of Clinical Pathologists (ASCP):

-. Chemistry:

a) plasma LH determination;
b) plasma FSH determination;
c) plasma estradiol, 17 beta determination;
d) plasma beta-hCG determinations.

2) Microbiology:

a) bacterialogical cultures of semen;
b) bacteriological cultures of cervix.

The remaining functions of the program are subject to JCAHO (Joint Commission for Accreditation of Health Organizations) accreditation processes within the accreditation of Magee-womens Hospital as a health care facility.

22.

It is not felt that a person of his qualifications requires supervision. We do have annual visits by Dr. Stephen Hillier who was instrumental in developing the IVF Laboratory in Hammersmith, London, England.

IVF/GIFT SURVEY

CLINIC NAME: Women & Infants Hospital / IVF Program
ADDRESS: Ray V. Haning Jr., M.D.
101 Dudley Street
Providence, Rhode Island 02905

CONTACT PERSON: Ray V. Haning Jr., M.D.
PHONE NUMBER: (401) 274-1100 Extension 1564

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/30/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ________
   (b) Community hospital based ________
   (c) University based X
   (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   (a) Physicians ________
   (b) Laboratory Scientists (PhDs) ________
   (c) Nurses 1
   (d) Embryo Lab Technicians/Technologists 2
   (e) Other Lab Technicians/Technologists ________
   (f) Radiology (Ultrasound) Technicians ________
   (g) Psychologists/Counselors ________
   (h) Secretaries 1
   (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 1 year and 9 months

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 2/87 GIFT -

9. How many different patients were stimulated?
1987 IVF 7 1988 IVF 11
GIFT - GIFT -

10. How many stimulation cycles were performed?
1987 IVF 9 1988 IVF 14
GIFT - GIFT -

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 9 1988 13

How many embryo transfer cycles were performed?
1987 6 1988 11

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 - 1988 -

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 4 57% 1988 IVF 7 63%
GIFT - -% GIFT - -%
(b) Endometriosis:
1987 IVF 1 14% 1988 IVF 2 18%
GIFT - ___% GIFT - ___%
(c) Male infertility:
1987 IVF 2 29% 1988 IVF 2 18%
GIFT - ___% GIFT - ___%
(d) Unexplained infertility:
1987 IVF 2 29% 1988 IVF 1 9%
GIFT - ___% GIFT - ___%
(e) Other (explain): -
1987 IVF - ___% 1988 IVF - ___%
GIFT - ___% GIFT - ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 1 14% 1988 IVF 5 46%
GIFT - ___% GIFT - ___%
(b) 31-35:
1987 IVF 4 57% 1988 IVF 4 36%
GIFT - ___% GIFT - ___%
(c) 36-40:
1987 IVF 1 14% 1988 IVF 2 18%
GIFT - ___% GIFT - ___%

(d) 41-45:
1987 IVF 1 14 % 1988 IVF - ___ %
GIFT - ___ % GIFT - ___ %

(e) >45:
1987 IVF - ___ % 1988 IVF - ___ %
GIFT - ___ % GIFT - ___ %

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 3
GIFT - GIFT -

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT - GIFT -

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 3
GIFT - GIFT -

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT - GIFT -

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___ % ______________________
GIFT - ___ % ______________________

1988 IVF 0 ___ % ______________________
GIFT - ___ % ______________________

21. What are the qualifications of the director of the embryo laboratory? M.D., Board Certified Reproductive Endocrinologist, Board Certified Obstetrician/Gynecologist

22. Who supervises the laboratory director? The laboratory director is also Section Chief of Reproductive Endocrinology.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? No

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Not eligible, due to start up status of the clinic.

27. Does the clinic train individuals in IVF or GIFT? No

If the answer is yes, how many individuals in the following specialties have been trained?

(a) Physicians ________

(b) Laboratory scientists (PhDs) ______

(c) Embryo laboratory technicians/technologists _____

(d) Nurses _______

(e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The Women and Infants Hospital IVF program is a new program with a small number of completed patient cycles and a small but competent staff. Women and Infants Hospital is the main teaching hospital for Obstetrics and Gynecology for Brown University, and the Women and Infants Hospital IVF program is the first and only IVF program in Rhode Island. The director of the program is Dr. Ray V. Haning, Jr., M.D. who is Associate professor of Obstetrics and Gynecology at Brown University and Director of the Section of Reproductive Endocrinology. The associate director of the program is Dr. Jacquelyn Loughlin, M.D. who is an assistant professor of Obstetrics and Gynecology at Brown University. Both are board certified in Obstetrics and Gynecology and both have subspecialty board recognition in Reproductive Endocrinology. Prior to instituting the program at Women and Infants Hospital, patients had to go out of state to obtain IVF services. Since institution of Lupron/Pergonal/Metrodin for induction of ovulation in May, 1988, 27% of embryo transfer cycles have resulted in ongoing pregnancies and another 18% of embryo transfer cycles have resulted in biochemical pregnancies. Embryo transfers have occurred in 100% of cycles brought to egg retrieval and our cancellation rate prior to oocyte retrieval is 8%. Our first pregnancies are due in February, 1989.

IVF/GIFT SURVEY

CLINIC NAME: MUSC IVF Program

ADDRESS: Department of Ob/Gyn
171 Ashley Ave.
Charleston, S.C. 29425

CONTACT PERSON: Charles C. Tsai, M.D.

PHONE NUMBER: 803-792-8351

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? January 8, 1989
2. Does your clinic perform IVF/GIFT treatments? Yes
   (If the answer is no, there is no need to complete the remainder of the questionnaire.)
3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______
4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? Two
5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? Two
6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 4
   - (d) Embryo Lab Technicians/Technologists 0(pending replacement)
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 1
   - (i) Other (specify) ______
7. How many years has your infertility clinic been in operation? 4
8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF November, 1984 GIFT ______

9. How many different patients were stimulated?
1987 IVF 7 **1988 IVF** 10
GIFT 0 **GIFT** 0

10. How many stimulation cycles were performed?
1987 IVF 15 **1988 IVF** 13
GIFT 0 **GIFT** 0

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 11 **1988** 11

How many embryo transfer cycles were performed?
1987 8 **1988** 10

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 **1988** 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% **1988** 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 4 ___% **1988 IVF** 7 ___%
GIFT ___ ___% **GIFT** ___ ___%
(b) Endometriosis:
1987 IVF 2 ___% **1988 IVF** ___ ___%
GIFT ___ ___% **GIFT** ___ ___%
(c) Male infertility:
1987 IVF ___ ___% **1988 IVF** 3 ___%
GIFT ___ ___% **GIFT** ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% **1988 IVF** ___ ___%
GIFT ___ ___% **GIFT** ___ ___%
(e) Other (explain): Cervical stenosis
1987 IVF 1 ___% **1988 IVF** ___ ___%
GIFT ___ ___% **GIFT** ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 ___% **1988 IVF** 1 ___%
GIFT ___ ___% **GIFT** ___ ___%
(b) 31-35:
1987 IVF 2 ___% **1988 IVF** 1 ___%
GIFT ___ ___% **GIFT** ___ ___%
(c) 36-40:
1987 IVF 5 ___% **1988 IVF** 4 ___%
GIFT ___ ___% **GIFT** ___ ___%

(d) 41-45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 1 1988 IVF 2
GIFT ___ GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 2
GIFT ___ GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 1 1988 IVF 1
GIFT ___ GIFT ___

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT ___ GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___% ______________
GIFT ___ ___% ______________

1988 IVF 0 ___% ______________
GIFT ___ ___% ______________

21. What are the qualifications of the director of the embryo laboratory? Ph.D. degree in biological sciences

22. Who supervises the laboratory director? ______________

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? *Yes*

27. Does the clinic train individuals in IVF or GIFT? *Yes*
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians *1*
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: SOUTHEASTERN FERTILITY CENTER
ADDRESS: 900 BOWMAN RD., SUITE 108
MT. PLEASANT, SC 29464

CONTACT PERSON: KAREN CAINES - IVF/GIFT COORDINATOR
PHONE NUMBER: # 803-881-3900

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/24/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ✓
   - (b) Community hospital based ____
   - (c) University based ____
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 3 FULLTIME ; 5 PART-TIME
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 2 - CONSULTANTS
   - (h) Secretaries 4
   - (i) Other (specify) 1 ADMINISTRATOR; 1 ASSIST. ADMINISTRATOR

7. How many years has your infertility clinic been in operation? 16 YRS. (SINCE 1972)

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1984 GIFT 1986

9. How many different patients were stimulated?
1987 IVF 39 1988 IVF 52
GIFT 12 GIFT 50

10. How many stimulation cycles were performed?
1987 IVF 50 1988 IVF 82
GIFT 13 GIFT 73

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 27 1988 41

How many embryo transfer cycles were performed?
1987 23 1988 33

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 11 1988 39

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 - % 1988 0 - %

14. What were the number and percentage of patients treated for:
(a) Tubal factor: (Completed IVF & GIFT cases- Data only available for these Pts.)
1987 IVF 18 67% 1988 IVF 34 83%
GIFT 3 27½% GIFT 1 3 %
(b) Endometriosis:
1987 IVF 1 4 % 1988 IVF 1 2½%
GIFT 3 27½% GIFT 12 31 %
(c) Male infertility:
1987 IVF 5 18 % 1988 IVF 5 12 %
GIFT 2 18 % GIFT 11 27 %
(d) Unexplained infertility:
1987 IVF 2 7 % 1988 IVF 1 2½%
GIFT 2 18% GIFT 7 18 %
(e) Other (explain): CERVICAL; POLYCYSTIC OVARIAN DISEASE
1987 IVF 1 4 % 1988 IVF 0 0 %
GIFT 1 9 % GIFT 8 21 %

15. What were the number and percentage of patients in the following age groups: Data only available on Completed IVF & GIFT cases)
(a) <31:
1987 IVF 6 22% 1988 IVF 7 17 %
GIFT 4 36 % GIFT 8 21 %
(b) 31-35:
1987 IVF 12 44% 1988 IVF 20 49 %
GIFT 5 46 % GIFT 21 53 %
(c) 36-40:
1987 IVF 8 30% 1988 IVF 10 24%
GIFT 2 18 % GIFT 8 21 %

(d) 41-45:
1987 IVF 1 4 % 1988 IVF 4 10 %
GIFT 0 – % GIFT 2 5 %
(e) >45:
1987 IVF 0 – % 1988 IVF 0 – %
GIFT 0 – % GIFT 0 – %

16. How many clinical pregnancies were produced?
1987 IVF 3 1988 IVF 2
GIFT 2 GIFT 15 (PLUS 2 BIOCHEMICAL)

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 1 1988 IVF 1
GIFT 2 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 11

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 – %
GIFT 0 – %

1988 IVF 0 – %
GIFT 4 27 % (3 ONGOING, 1 DELIVERED)

21. What are the qualifications of the director of the embryo laboratory? Ph.-D, EMBRYOLOGIST, WITH YRS OF SUCCESS IN IVF

22. Who supervises the laboratory director? DIRECTOR & ASSIST. DIRECTOR OF CENTER

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? YES

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** YES

27. **Does the clinic train individuals in IVF or GIFT?** NO **If the answer is yes, how many individuals in the following specialties have been trained?**
    - **(a) Physicians** ________
    - **(b) Laboratory scientists (PhDs)** ________
    - **(c) Embryo laboratory technicians/technologists** _____
    - **(d) Nurses** ________
    - **(e) Other (explain)** ________

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

IN OUR RECENT EXPERIENCE WITH SUCCESSFUL G.I.F.T. CASES, WE HAVE FOUND DIAGNOSIS TO CORRELATE DIRECTLY WITH PROGNOSIS AS OPPOSED TO THE AGE OF THE PATIENT. QUALITY OF THE STIMULATION IS ALSO A KEY FACTOR IN ACHIEVING A PREGNANCY. WE HAVE FOUND IT IS THE QUALITY OF THE STIMULATION THAT STRONGLY CORRELATES, RATHER THAN THE NUMBER OF STIMULATIONS.

IVF/GIFT SURVEY

CLINIC NAME: East Tennessee State University College of Medicine
ADDRESS: OB/GYN Department
Box 19570A
Johnson City, TN 37614

CONTACT PERSON: Dr. Sam Thatcher or Dr. Gary Randall
PHONE NUMBER: (615) 929-6659

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 15 Feb 89

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 4
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 3 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 14 March 1986 GIFT 27 June 1986

9. How many different patients were stimulated?
1987 IVF 22 1988 IVF 10
GIFT 1 GIFT 3

10. How many stimulation cycles were performed?
1987 IVF 24 1988 IVF 14
GIFT 1 GIFT 3

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 21 1988 12

How many embryo transfer cycles were performed?*
1987 13 1988 6
*Transfer of cleaving conceptuses only

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 3

13. What were the number and percentage of patients on IRB approved research protocols?
1987 21 100 % 1988 12 100%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 11 50 % 1988 IVF 6 60%
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 4 18 % 1988 IVF 1 10 %
GIFT 0 0 % GIFT 2 20 %
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 2 10 % 1988 IVF 1 10 %
GIFT 1 4 % GIFT 1 10 %
(e) Other (explain): combined
1987 IVF 5 22 % 1988 IVF 2 20 %
GIFT 0 0 % GIFT 0 0 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 5 23 % 1988 IVF 2 20 %
GIFT 0 0 % GIFT 1 10 %
(b) 31-35:
1987 IVF 11 50 % 1988 IVF 3 30 %
GIFT 1 4 % GIFT 1 10 %
(c) 36-40:
1987 IVF 4 18 % 1988 IVF 3 30 %
GIFT 0 0 % GIFT 1 10 %

(d) 41-45:
1987 IVF 2 1 % 1988 IVF 2 2 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 1 1988 IVF 1
GIFT 0 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 %
GIFT 0 0 %

1988 IVF 1 100 % twins, ongoing at 26 weeks
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? M.S., Physiology, Ph.D. Reproductive Physiology, Postdoctoral work in Andrology

22. Who supervises the laboratory director? IVF Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
Endocrine and Andrology laboratories are monitored by the College of American Pathologists and licensed by the State of Tennessee

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 0
    (b) Laboratory scientists (PhDs) 2
    (c) Embryo laboratory technicians/technologists 1
    (d) Nurses 0
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

In our first year of operation, 1986, there were three term pregnancies in 15 transfer cycles transferred after IVF. One pregnancy is ongoing at 10 weeks. To date, 6 term (1 pregnancy ongoing at 26 weeks) pregnancies, including 1 ectopic have been achieved in 50 transfers after IVF.

note: This report is for the Clinic @ East Tn Baptist Hospital. This was terminated in May 1988 due to problems with use of frozen semen + embryo freezing. We have restarted the program recently at another hospital

IVF/GIFT SURVEY

CLINIC NAME: Family Life Center
ADDRESS: East Tennessee Baptist Hospital
Box 1788
Knoxville, TN 37901

CONTACT PERSON: J. Ray King, M.D.
PHONE NUMBER: (615) 573-0031

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the never clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? June 1988

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 0
Have been recruiting for 2 yrs, none available

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists ~~0~~ 1
   - (e) Other Lab Technicians/Technologists 0
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 3

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF X GIFT ______

From September 1984
through March 1988
IVF = 33 cycles begun
27 egg recoveries
25 fertilization occurred
25 transfers
2 pregnancy
GIFT = 65 cycles begun
47 egg recoveries
47 gamete transfers
6 pregnancies

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF _______
GIFT _____ GIFT ______

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF _______
GIFT _____ GIFT ______

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ________ 1988 ________

How many embryo transfer cycles were performed?
1987 ________ 1988 ________

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ________ 1988 _________

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
- (a) Tubal factor:
  1987 IVF ___ ___% 1988 IVF ___ __%
  GIFT ___ ___% GIFT ___ ___%
- (b) Endometriosis:
  1987 IVF ___ ___% 1988 IVF ___ ___%
  GIFT ___ ___% GIFT ___ ___%
- (c) Male infertility:
  1987 IVF ___ ___% 1988 IVF ___ ___%
  GIFT ___ ___% GIFT ___ ___%
- (d) Unexplained infertility:
  1987 IVF ___ ___% 1988 IVF ___ ___%
  GIFT ___ ___% GIFT ___ ___%
- (e) Other (explain): ______________________
  1987 IVF ___ ___% 1988 IVF ___ ___%
  GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
- (a) <31:
  1987 IVF ___ ___% 1988 IVF ___ ___%
  GIFT ___ ___% GIFT ___ ___%
- (b) 31-35:
  1987 IVF ___ ___% 1988 IVF ___ ___%
  GIFT ___ ___% GIFT ___ ___%
- (c) 36-40:
  1987 IVF ___ ___% 1988 IVF ___ ___%
  GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

19. How many ectopic pregnancies resulted?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT ____

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ____________
GIFT ___ ___% ____________

1988 IVF ___ ___% ____________
GIFT ___ ___% ____________

21. What are the qualifications of the director of the embryo laboratory? Professor of Zoology, Univ. of TN, Knoxville - Expertise in sperm-egg interaction, especially zona binding & blocking

22. Who supervises the laboratory director? himself - (small program)

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? NO - no Reproductive Endocrinologist

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** NO

27. **Does the clinic train individuals in IVF or GIFT?** NO
If the answer is yes, how many individuals in the following specialties have been trained?
    - **(a) Physicians** ________
    - **(b) Laboratory scientists (PhDs)** ________
    - **(c) Embryo laboratory technicians/technologists** _____
    - **(d) Nurses** ______
    - **(e) Other (explain)** ________

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

The program was begun in 1985 as our community had two interested experienced Embryo scientists. Dr. Alex Shivers and Dr. Joseph Daniller. Both of these persons have had extensive experience in egg-sperm interaction embryo handling and implantation ~~physiology~~ physiology.

I, as a Ob-Gyn, have kept current with infertility since my training (1968-71), before there was much to do for infertility couples and no fellowship training programs established.

Success rates for IVF are disappointing. Have had two pregnancies; one baby, one ectopic.

Gift success rates ~~not~~ better.

Need Reproductive Endocrinologist for general infertility and clinical practice, to help IVF/GIFT program. Fellows in REproductive Endocrine are "programmed" and pressured to stay in "Academic" roles to obtain their Boards. Few are interested in Private Practice.

I personally feel comfortable in my work, just overworked. I have attended courses, read literature, referred when needed and have attempted to be honest and competent.

We need some regulations, but remember that Reproductive Endocrine Training does not foreclose competence in reproductive practice. Leave a little leeway for those of us who have "grown-up" with modern infertility practice.

IVF/GIFT SURVEY

CLINIC NAME: Univ. of Tennessee Fertility Center
ADDRESS: 1924 Alcoa Highway, U-27
Knoxville, TN 37920

CONTACT PERSON: Michael C. Doody, M.D., Ph.D. , Pat Dalton, RN, BSN.
PHONE NUMBER: (615)544-9305

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Present

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    (a) Private ______
    (b) Community hospital based ______
    (c) University based X
    (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 0

6. How many other professionals participate in your clinic?
    (a) Physicians 2
    (b) Laboratory Scientists (PhDs) 1
    (c) Nurses 4
    (d) Embryo Lab Technicians/Technologists 1
    (e) Other Lab Technicians/Technologists ______
    (f) Radiology (Ultrasound) Technicians ______
    (g) Psychologists/Counselors 1
    (h) Secretaries 2
    (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 1

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 11/87 GIFT 2/88

9. How many different patients were stimulated?
1987 IVF 3 1988 IVF 5
GIFT 0 GIFT 0
GIFT/IVF 8

10. How many stimulation cycles were performed?
1987 IVF 3 1988 IVF 1
GIFT 0 GIFT ___
GIFT/IVF 15

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 1 1988 13

How many embryo transfer cycles were performed?
1987 1 1988 13

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 0 (GIFT only)
8 (IVF-GIFT)

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 2 66% 1988 IVF 7 54%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 2 66% 1988 IVF 9 69% (GIFT-IVF cycles
GIFT ___ ___% GIFT ___ ___% attributed to
IVF only)
(c) Male infertility:
1987 IVF 2 66% 1988 IVF 9 69%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): Multliple factors (≥ 3 factors)
1987 IVF 3 100% 1988 IVF 12 92%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 1 33% 1988 IVF 2 15% (GIFT-IVF cycles
GIFT ___ ___% GIFT ___ ___% attributed to
IVF only)
(b) 31-35:
1987 IVF 0 0% 1988 IVF 8 62%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF 1 33% 1988 IVF 2 15%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF 1 33 % 1988 IVF 1 8 %
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___% ______________________
GIFT 0 ___% ______________________

1988 IVF 0 ___% ______________________
GIFT 0 ___% ______________________

21. What are the qualifications of the director of the embryo laboratory? M.D., Ph.D. Member of American Association of Tissue Banks, Reproductive Council, Board eligible reproductive endocrinologist.

22. Who supervises the laboratory director? ______________________

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
Media screened for endotoxin externally.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** No

27. **Does the clinic train individuals in IVF or GIFT?** Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    - **(a) Physicians** ________
    - **(b) Laboratory scientists (PhDs)** ________
    - **(c) Embryo laboratory technicians/technologists** 1
    - **(d) Nurses** 1
    - **(e) Other (explain)** ________

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

RECEIVED

8 1988

Hon Ron Wyden

IVF/GIFT SURVEY

CLINIC NAME: Center for Fertility and Reproductive Research

ADDRESS: D-3200, Medical Center North
Vanderbilt University Medical Center
Nashville, Tennessee 37232

CONTACT PERSON: Dr. Anne Colston Wentz

PHONE NUMBER: 615/322-6576

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/22/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based x
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 5

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 5
   - (d) Embryo Lab Technicians/Technologists 3
   - (e) Other Lab Technicians/Technologists 5
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 7

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 2/1982 GIFT 1/1986

9. How many different patients were stimulated?
1987 IVF 97 1988 IVF 97
GIFT 24 GIFT 14

10. How many stimulation cycles were performed?
1987 IVF 127 1988 IVF 126
GIFT 33 GIFT 16

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 99 1988 116

How many embryo transfer cycles were performed?
1987 78 1988 100

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 25 1988 14

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 100% 1988 ___ 100%

14. What were the number and percentage of patients treated for:

Many patients have more than one diagnosis.

(a) Tubal factor:
1987 IVF 40 41.2% 1988 IVF 46 47.4%
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 30 31 % 1988 IVF 53 23.7%
GIFT 14 58.3% GIFT 6 42.9%
(c) Male infertility:
1987 IVF 21 22 % 1988 IVF 36 37.1%
GIFT 0 0 % GIFT 2 14.3%
(d) Unexplained infertility:
1987 IVF 11 11.3% 1988 IVF 6 6.18%
GIFT 16 66.7% GIFT 6 42.9%
(e) Other (explain): Pelvic Adhesions
1987 IVF 34 35 % 1988 IVF 18 18.6%
GIFT 4 16.7% GIFT 2 1.5%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 27 27.8% 1988 IVF 26 26.8%
GIFT 4 16.7% GIFT 5 35.7%
(b) 31-35:
1987 IVF 41 42.3% 1988 IVF 48 49.5%
GIFT 13 54.2% GIFT 3 21.4%
(c) 36-40:
1987 IVF 31 32 % 1988 IVF 19 19.6%
GIFT 6 23.1% GIFT 5 35.7%

(d) 41-45:
1987 IVF 4 4.1% 1988 IVF 2 2.1 %
GIFT 1 4.2 % GIFT 1 7.1%
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 8 1988 IVF 18
GIFT 4 GIFT 4

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 11 1988 IVF 12
GIFT 1 GIFT 4

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 12
GIFT 0 GIFT 2

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 2
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 18 % twins
GIFT 0 0 %

1988 IVF 2 17 % twins
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Biochemistry; Post Doc. in Reproductive Biology

22. Who supervises the laboratory director? Anne Colston Wentz, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
- **(a) Physicians** 6
- **(b) Laboratory scientists (PhDs)** 2
- **(c) Embryo laboratory technicians/technologists** 10
- **(d) Nurses** 2
- **(e) Other (explain)** ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Vanderbilt's C-FARR Clinic sees a large number of male infertility patients. IVF is indicated for diagnosis of fertilization capacity, as well as treatment for some of these patients. Therefore, fertilization rates and pregnancy rates may be decreased compared to rates in clinics which do not accept couples with male infertility for IVF.

IVF/GIFT SURVEY

CLINIC NAME: Program for Advanced Infertility & Reproduction (PAIR)
ADDRESS: 66 North Pauline
Memphis, TN 38105

CONTACT PERSON: Sandra Ann Carson, M.D.
PHONE NUMBER: (901) 528-6634

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/1/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   - (a) Physicians 3
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists ______
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors (peripherally)
   - (h) Secretaries ______
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 3 Months

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF Sept., 1988 GIFT Oct. - Feb., 1988 then Sept., 1988

We stopped for about 1 year until IVF was ready.

9. How many different patients were stimulated?
1987 IVF 0 1988 IVF 12
GIFT 3 GIFT 6

10. How many stimulation cycles were performed?
1987 IVF 0 1988 IVF 14
GIFT 3 GIFT 6

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 0 1988 12

How many embryo transfer cycles were performed?
1987 0 1988 11

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 3 1988 5

13. What were the number and percentage of patients on IRB approved research protocols? IRB refused to review our protocols.
1987 N/A ___% 1988 N/A ___% They said this was a clinical procedure.

14. What were the number and percentage of patients treated for:

NOTE: Each couple may have had more than one problem.

(a) Tubal factor:
1987 IVF 0 ___% 1988 IVF 11 85%
GIFT 0 ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 2 15%
GIFT 1 33% GIFT 4 67%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 5 38%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 2 67% GIFT 2 33%
(e) Other (explain): ___
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF 1 8%
GIFT 1 33% GIFT 1 17%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF 5 42%
GIFT 1 33% GIFT 3 50%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF 6 50%
GIFT 1 33% GIFT 2 33%

(d) 41-45:
1987 IVF 0 ___ % 1988 IVF 0 ___ %
GIFT 0 ___ % GIFT 0 ___ %

(e) >45:
1987 IVF 0 ___ % 1988 IVF 0 ___ %
GIFT 0 ___ % GIFT 0 ___ %

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 2
GIFT 0 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF N/A 1988 IVF N/A (too soon to deliver)
GIFT 0 GIFT N/A

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ______________
GIFT ___ ___% 0

1988 IVF ___ ___% N/A
GIFT ___ ___% N/A

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in related science; embryo handling and gamete handling experience; tissue culture experience

22. Who supervises the laboratory director? M.D. - Reproductive Endocrinologist (Dr. Carson)

23. Does the clinic participate in an external laboratory proficiency testing program? ______________
If the answer is yes, please specify which program.
Yes - endotoxin testing, HPLC testing, mouse assay testing

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** We cannot be a member because we use an Apple Computer not an IBM. We would very much like to join.

27. **Does the clinic train individuals in IVF or GIFT?** yes
If the answer is yes, how many individuals in the following specialties have been trained?
    - **(a) Physicians** currently 2
    - **(b) Laboratory scientists (PhDs)** -
    - **(c) Embryo laboratory technicians/technologists** -
    - **(d) Nurses** -
    - **(e) Other (explain)** -

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

Our laboratory is unique in that it was specifically designed for IVF. It has two HEPA filtered rooms, one at 80% for media preparation and the other embryo room at 95%. We employ vigorous quality control which utilizes human sperm, as well as mouse embryo testing. Our dual lighting system prevents embryos from being exposed to fluorescent lighting. We allow no one in the embryo laboratory during a cycle except a member of the IVF team. All procedures are performed in the Outpatient IVF suite.

IVF/GIFT SURVEY

CLINIC NAME: St. David's Community Hospital IVF/GIFT Program
ADDRESS: P.O. Box 4039
Austin, Texas 78765

CONTACT PERSON: Ruby Fischer, RNP/Thomas C. Vaughn, M.D.
PHONE NUMBER: (512) 397-4127 (512) 451-0955

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11-3-88 (stimulations

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ____
   (b) Community hospital based X
   (c) University based ____
   (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1 - Board Certified

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4 (including above M.D.)

6. How many other professionals participate in your clinic?
   (a) Physicians 0 (only the 4 mentioned above)
   (b) Laboratory Scientists (PhDs) 0
   (c) Nurses 1.5
   (d) Embryo Lab Technicians/Technologists 2
   (e) Other Lab Technicians/Technologists 0
   (f) Radiology (Ultrasound) Technicians 0
   (g) Psychologists/Counselors 0
   (h) Secretaries (Assistant) .5
   (i) Other (specify) 0

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF Fall 1984 GIFT 1986

9. How many different patients were stimulated?
1987 ~~IVF~~ ______ 1988 ~~IVF~~ ______
~~GIFT~~ ______ ~~GIFT~~ ______ +Tubal Embryo Transfer
Both IVF & GIFT pts. = 99 Both IVF & GIFT pts. = 128

10. How many stimulation cycles were performed?
1987 IVF 30 1988 IVF 75
GIFT 82 GIFT 6 IVF/TET - 4
GIFT/IVF COMBO - 14 GIFT/IVF COMBO - 71 (Tubal Embryo Transfer or "ZIFT")

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 90 1988 116

How many embryo transfer cycles were performed?
1987 19 (IVF) 1988 52

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 59 1988 4
GIFT/IVF COMBO - 12 GIFT/IVF COMBO - 56, TET - 4

13. What were the number and percentage of patients on IRB approved research protocols? N/A
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:

DATA UNAVAILABLE

(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ______
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:

DATA UNAVAILABLE

(a) <31:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF __ __% 1988 IVF __ __%
GIFT __ __% GIFT __ __%

(e) >45:
1987 IVF __ __% 1988 IVF __ __%
GIFT __ __% GIFT __ __%

16. How many clinical pregnancies were produced?
1987 IVF 4 1988 IVF 12
GIFT 6 GIFT 0
GIFT/IVF COMBO - 4 GIFT/IVF COMBO - 25, TET - 3

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 4 1988 IVF 2
GIFT 6 GIFT 0
GIFT/IVF COMBO - 3 GIFT/IVF COMBO - 10, TET - 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 8
GIFT 0 GIFT 0
GIFT/IVF COMBO - 11, TET - 3

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 1 GIFT 0
GIFT/IVF COMBO - 1

20. What were the number, percentage of all births, and plurality, of multiple births?

1987	IVF	2	50 %	1-twins, 1-triplets
	GIFT	0	0 %	
	COMBO	1	33	1-twins
1988	IVF	0	0 %	
	GIFT	0	0 %	
	COMBO	2	20	2-twins

21. What are the qualifications of the director of the embryo laboratory? Over 20 years experience in a university research laboratory, working largely with in vitro animal experiments & andrology work (before human in vitro fertilization).

22. Who supervises the laboratory director? Medical Director

23. Does the clinic participate in an external laboratory proficiency testing program? No - inhouse
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** Yes

27. **Does the clinic train individuals in IVF or GIFT?** Yes*
If the answer is yes, how many individuals in the following specialties have been trained?
    - **(a) Physicians** ________
    - **(b) Laboratory scientists (PhDs)** ________
    - **(c) Embryo laboratory technicians/technologists** 1
    - **(d) Nurses** ________
    - **(e) Other (explain)** ________

*For our program.

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

St. David's IVF/GIFT Program has demonstrated a significantly higher pregnancy rate in our patients who combine In Vitro Fertilization/Embryo Transfer WITH their GIFT treatment. The cost is the same as an In Vitro Fertilization/Embryo Transfer treatment. Usually 2-3 eggs with sperm are transferred into the fallopian tubes during a laparoscopy, and 2-3 eggs are fertilized in vitro with subsequent transfer of 2-3 embryos 48 hours post retrieval. This "Combo" procedure has been useful in demonstrating fertilization capacity and has consistently produced higher continuing pregnancy rates than either GIFT or IVF/ET alone in our program.

ZIFT (or, In Vitro Fertilization and Tubal Embryo Transfer) was offered for the first time in the fall of 1988. While numbers were extremely small (3 pregnancies in 4 patients), initial results look very promising, and the procedure will continue to be offered to those women with a normal fallopian tube.

To date, St. David's Community Hospital's Program has been able to serve couples as they apply, without a waiting period. Evaluation of the couples, planning, and preparation for their treatments typically is accomplished within four to six weeks.

IVF/GIFT SURVEY

CLINIC NAME: Trinity Invitro Fertilization/Embryo Transfer Program
ADDRESS: 4333 N. Josey Lane Suite 200
Carrollton, Texas
75010

CONTACT PERSON: Catherine Strain RNP
PHONE NUMBER: (214) 394-0114 or (214) 394-8483 (IVF line)

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 2/13/89

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 0 (with exception of 2 RE previously mentioned)

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 5
   - (f) Radiology (Ultrasound) Technicians 3
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 1
   - (i) Other (specify) 3 - OR tech

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1985

9. How many different patients were stimulated?
1987 IVF 49 1988 IVF 118
GIFT 4 GIFT 12

10. How many stimulation cycles were performed?
1987 IVF 56 1988 IVF 123
GIFT 4 GIFT 12

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 66 1988 107

How many embryo transfer cycles were performed?
1987 46 1988 83

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 4 1988 12

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 38 77.55% 1988 IVF 65 55.0%
GIFT 1 25.0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 27 55.10% 1988 IVF 81 68.64%
GIFT 3 75 % GIFT 0 ___ %
(c) Male infertility:
1987 IVF 17 34.69% 1988 IVF 24 20.34%
GIFT 2 60 % GIFT 0 ___ %
(d) Unexplained infertility:
1987 IVF 0 ___ % 1988 IVF 13 11.01 %
GIFT 0 ___ % GIFT 12 100 %
(e) Other (explain): Antibodies
1987 IVF 26 53.06% 1988 IVF 11 9.32%
GIFT 3 75 % GIFT 0 ___ %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 12 24.48% 1988 IVF 18 15.25%
GIFT 1 25 % GIFT 2 16.67%
(b) 31-35:
1987 IVF 23 46.94% 1988 IVF 44 37.29%
GIFT 2 50 % GIFT 5 41.67%
(c) 36-40:
1987 IVF 14 28.57% 1988 IVF 32 27.11%
GIFT 1 25 % GIFT 5 41.67%

(d) 41-45:
1987 IVF 3 6.12% 1988 IVF 12 10.16%
GIFT 0 ___% GIFT 0 0%

(e) >45:
1987 IVF 1 2.04% 1988 IVF 0 0%
GIFT 0 0% GIFT 0 0%

16. How many clinical pregnancies were produced?
1987 IVF 11 1988 IVF 14
GIFT 1 GIFT 4

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 10 1988 IVF 7
GIFT 0 GIFT 3

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 7
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 10 22% I twin gestation, 9 singleton deliveries
GIFT 0 ___%

1988 IVF 7 17% 5 singleton & 2 twin delivered
GIFT 3 25% I singleton + 2 twin delivered

21. What are the qualifications of the director of the embryo laboratory? MT(ASCP) Post Graduate Course Embryology UTHSC, Dallas
Associated with IVF Clinic since Established.

22. Who supervises the laboratory director? Dr. Tom James

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
ASCP CAP Survey

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ________
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

See Attached

Texas Endocrine and Fertility Institute

Reproductive Endocrinology, Infertility, Microsurgery, Laser Gynecology, In Vitro Fertilization

W.F. (Dub) Howard, M.D.
H. Jane Chihal, M.D., Ph.D.

4333 N. Josey Lane, Suite 200
Carrollton, Texas 75010
(214) 394-0114

The Trinity IVF Program opened in late 1983. Our first pregnancy began in 1984 and was delivered in 1985. Subsequently, we have had 37 live births. We have been in operation under the same leadership since that time. We are the only consistently successful IVF/GIFT program in North Texas to date. Therefore, we are the only area program to achieve the status of membership in S.A.R.T., the society dedicated to maintaining IVF standards in the United States. We are also the only IVF/GIFT program in North Texas under the direction of only Reproductive Endocrinology specialists (W.F. (Dub) Howard M.D. and H. Jane Chihal M.D.).

Our program is dedicated to two guiding principles: 1) providing state-of-the-art fertility medicine, including ultrasound egg-recovery, cryopreservation of embryos, IVF/GIFT/ZIFT, and surrogate cycles, as well as all other up-to-date fertility treatment possibilities both surgical and nonsurgical. 2.) making the patient feel as comfortable as possible by providing a warm, understanding atmosphere to keep stress to a minimum. This also means keeping the cost as low as possible. Our unique "programmed cycles" allow patients to schedule their egg recoveries months in advance thereby reducing the stress of not knowing when the cycle will begin ... we make it begin on time!! Yet at the same time, we can individualize the cycle to the patients needs, and our consistent pregnancy rate compares favorably with much larger programs throughout the world.

At Trinity you, the patient, are treated as an individual, not as a number. We do this by limiting the number of cycles performed each month and by providing adequate numbers of informed, caring team members to work with you as a person.

Quality of care is never compromised at Trinity. Members of our team attend all major and some minor IVF conferences and are each faculty members of an annual IVF/GIFT symposium offered here and attended by physicians from all over the United States. All of this knowledge is applied to our program, so that it will remain state-of-the-art.

If you have questions about our program and/or wish to enroll call our IVF/GIFT hotline at (214)394-8483.

BEST AVAILABLE COPY

IVF/GIFT SURVEY

CLINIC NAME: Presbyterian Hospital of Dallas
ADDRESS: c/o James D. Madden, M.D.
8160 Walnut Hill Ln., Suite 320
Dallas, Tx 75231

CONTACT PERSON: James D. Madden, M.D.
PHONE NUMBER: (214) 363-6322

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 10/31/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 6

6. How many other professionals participate in your clinic?
   - (a) Physicians 1
   - (b) Laboratory Scientists (PhDs) 1(M.S.)
   - (c) Nurses 3
   - (d) Embryo Lab Technicians/Technologists 1(M.S.)
   - (e) Other Lab Technicians/Technologists ______
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors ______
   - (h) Secretaries 1/2
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 4

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 4/84 GIFT 7/85

9. How many different patients were stimulated?
1987 IVF 8 1988 IVF 3
GIFT 45 GIFT 43

10. How many stimulation cycles were performed?
1987 IVF 9 1988 IVF 3
GIFT 50 GIFT 49

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 3 1988 2

How many embryo transfer cycles were performed?
1987 3 1988 2

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 31 1988 24

13. What were the number and percentage of patients on IRB approved research protocols?
1987 11 21 % 1988 20 46.5 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 2 25 % 1988 IVF 2 66 %
GIFT 4 8.8 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 1 12 % 1988 IVF 1 33 %
GIFT 10 22 % GIFT 17 39.5 %
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 5 11 % GIFT 5 11.6 %
(d) Unexplained infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 10 22 % GIFT 6 13.9 %
(e) Other (explain): Ovulatory dysfunction/cervical factor
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 12 26.6 % GIFT 12 27.9 %

(f) Abnormal PCT & antisperm antibody
1987:
IVF 0 0%
GIFT 7 16%
1988:
IVF 0 0%
GIFT 2 4%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 1 12 % 1988 IVF 1 33 %
GIFT 5 11 % GIFT 7 16 %
(b) 31-35:
1987 IVF 1 12 % 1988 IVF 2 66 %
GIFT 20 44 % GIFT 15 34.8 %
(c) 36-40:
1987 IVF 1 12 % 1988 IVF 0 0 %
GIFT 20 44 % GIFT 21 48.8 %

(d) 41-45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

(e) >45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 0
GIFT 13 GIFT 11

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 11 GIFT 2

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 6

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 1 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 % ___
GIFT 6 54.5% 4/11(36.4%) twins: 2/11(18.1%) triplets

1988 IVF 0 0 % ___
GIFT ___ ___% one ongoing twin pregnancy

21. What are the qualifications of the director of the embryo laboratory? M.S. in biology. 1+ years experience with IVF/ET clinic in New Orleans (The Fertility Institute of New Orleans). Director of Assisted Reproductive Laboratory at this institution since 11/84.

22. Who supervises the laboratory director? medical/program director

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
See attached response.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Application in process

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Question #23: various consultants have visited the laboratory for the purposes of critique:

Ian Johnston, M.D. - 1984
Richard P. Marrs, M.D. - 11/27-28/1984
J. W. Edward Wortham, Jr., PhD - 9/13-16/85
A. I. Speirs - 10/9/87

Comments:

The average age at the time of conception through GIFT for women who have subsequently delivered was 34 years. The average duration of their infertility was 4.7 years.

The IVF/ET cases done in 1987 and 1988 were almost exclusively "failed GIFT procedures". That is, at the time of GIFT the oviducts appeared unacceptable with respect to the transfer of gametes and the case reverted to IVF.

The program will resume IVF treatment cycles for patients with irreversible tubal damage in 1989 on completion of a newly renovated culture laboratory.

IVF/GIFT SURVEY

CLINIC NAME: Department of Obstetrics and Gynecology
ADDRESS: Division of Reproductive Endocrinology
Univ. Texas Southwestern Medical School
Dallas, TX
75235
CONTACT PERSON: Dr. Janelle Odom
PHONE NUMBER: 214-688-8791

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Dec 1988

2. Does your clinic perform IVF/GIFT treatments? Yes.
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X Medical School.
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? Four

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 16

6. How many other professionals participate in your clinic?
   - (a) Physicians 24
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 5
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 3
   - (i) Other (specify) 1 patient coordination for infertility

7. How many years has your infertility clinic been in operation? 4

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1985 GIFT 1987

9. How many different patients were stimulated?
1987 IVF 14 1988 IVF 30
GIFT 7 GIFT 2

10. How many stimulation cycles were performed?
1987 IVF 14 1988 IVF 30
GIFT 7 GIFT 2

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 11 1988 26

How many embryo transfer cycles were performed?
1987 11 1988 18

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 7 1988 2

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 5 45.4% 1988 IVF 12 46%
GIFT 0 [illegible]% GIFT 0 ___%
(b) Endometriosis:
1987 IVF 1 9.1% 1988 IVF 3 11.5%
GIFT 7 100% GIFT 2 100%
(c) Male infertility:
1987 IVF 3 27.2% 1988 IVF 8 31%
GIFT 0 ___% GIFT 0 ___%
(d) Unexplained infertility:
1987 IVF 2 18.2% 1988 IVF 3 11.5%
GIFT 0 ___% GIFT 0 ___%
(e) Other (explain): ~~[illegible]~~
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 0 ___% GIFT 0 ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 1 9.1% 1988 IVF 3 11.5%
GIFT 0 ___% GIFT 1 50%
(b) 31-35:
1987 IVF 7 64% 1988 IVF 17 65%
GIFT 7 100% GIFT 1 50%
(c) 36-40:
1987 IVF 3 27% 1988 IVF 6 23%
GIFT 0 ___% GIFT 0 ___%

(d) 41-45:
1987 IVF 0 __% 1988 IVF 0 __%
GIFT 0 __% GIFT 0 __%

(e) >45:
1987 IVF 0 __% 1988 IVF 0 __%
GIFT 0 __% GIFT 0 __%

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 5
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 5
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 __% ____________
GIFT 0 __% ____________

1988 IVF 3 60% triplets, twins, twins.
GIFT 0 __% ____________

21. What are the qualifications of the director of the embryo laboratory? Ph.D in Zoology, 7 years hands on experience in human IVF, 55 publications

22. Who supervises the laboratory director? Dr. Bruce Carr Director.

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
State of Texas Laboratory Certification, Applications to CAP and AATB

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes.

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Will qualify in Jan 1989.

27. Does the clinic train individuals in IVF or GIFT? Yes.
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 4
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 1
    (d) Nurses 3
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

We offer a full service Infertility clinic. Couples referred to us are thoroughly evaluated by both our reproductive endocrinologists and our urologist before specific treatments are recommended. Possible treatments might include artificial insemination by donor, artificial insemination by husband, controlled ovarian stimulation or reconstructive surgery before we would recommend In Vitro Fertilization. Our artificial insemination by donor clinic uses sperm that we prepare and bank for a minimum of six months before use in accordance with the guidelines of the American Fertility Society and the American Association of Tissue Banks. With our current success rate we expect to expand the number of patients that undergo ultrasound-guided follicular aspiration and in vitro fertilization. We also offer embryo cryobanking facilities.

IVF/GIFT SURVEY

CLINIC NAME: Scott & White Clinic
Texas A&M College of Medicine
ADDRESS: 2401 South 31st Street
Temple, Texas 76508

CONTACT PERSON: Dr. Thomas J. Kuehl
PHONE NUMBER: (817) 774-3321

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? February 1, 1989

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based ______
   (c) University based X
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2 directly in section + 10 additional within department

6. How many other professionals participate in your clinic?
   (a) Physicians 10
   (b) Laboratory Scientists (PhDs) 3
   (c) Nurses 4
   (d) Embryo Lab Technicians/Technologists 2
   (e) Other Lab Technicians/Technologists 6
   (f) Radiology (Ultrasound) Technicians 0
   (g) Psychologists/Counselors 2
   (h) Secretaries 3 equivalents
   (i) Other (specify) --

7. How many years has your infertility clinic been in operation? 5 yrs.

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF Sept., 1988 GIFT Sept., 1988

9. How many different patients were stimulated?
1987 IVF 0 1988 IVF 3
GIFT 0 GIFT 3

10. How many stimulation cycles were performed?
1987 IVF ___ 1988 IVF 4
GIFT ___ GIFT 3

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 0 1988 3

How many embryo transfer cycles were performed?
1987 0 1988 3

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 2

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 * % 1988 0 %

* As a policy, no percentages will be reported until a minimum of 25 cycles have gone to surgery in each group.

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 0 ___% 1988 IVF 3 [illegible]%
GIFT 0 ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 3 [illegible]%
(c) Male infertility:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%
(d) Unexplained infertility:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%
(e) Other (explain): ____________
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 ___% 1988 IVF 1 33%
GIFT 0 ___% GIFT 3 ___%
(b) 31-35:
1987 IVF 0 ___% 1988 IVF 2 ___%
GIFT 0 ___% GIFT 0 ___%
(c) 36-40:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

(d) 41-45: **
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45: **
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

** As a policy, female patients over 40 are not offered IVF or GIFT at our institution.

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 2

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births? **
1987 IVF 0 ___% ______________________
GIFT 0 ___% ______________________

1988 IVF 0 ___% ______________________
GIFT 0 ___% ______________________

** First births due summer 1989. All pregnancies to date are singleton based on ultrasonic scan.

21. What are the qualifications of the director of the embryo laboratory? Ph. D. in Reproductive Physiology; first to produce in-vitro fertilized nonhuman primate embryos in 1972; first to produce nonhuman primate infant from IVF/ET in 1983; 17 years experience in (cont. on back)

22. Who supervises the laboratory director? Division director and Departmental chairman

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
Laboratories monitored and inspected by CAP surveys.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** No

27. **Does the clinic train individuals in IVF or GIFT?** Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) **Physicians** --
    (b) **Laboratory scientists (PhDs)** --
    (c) **Embryo laboratory technicians/technologists** 2
    (d) **Nurses** 1
    (e) **Other (explain)** --

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

Scott & White Clinic has recently added IVF/GIFT to its program of services in Obstetrics and Gynecology. This program like others at Scott & White was established and is being operated to provide high quality health care.

cont. #21. mammalian embryology and direct experience in 3 successful human IVF/GIFT programs.

IVF/GIFT SURVEY

CLINIC NAME: J.B. Belue M.D.
ADDRESS: 120 E. Charnwood
Tyler, Texas 75701

CONTACT PERSON: Dr. Belue, Sandy Wilson R.N.
PHONE NUMBER: 214-597-8371

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/88

2. Does your clinic perform IVF/[✓ GIFT] treatments? GIFT
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    - (a) Private x
    - (b) Community hospital based ________
    - (c) University based ________
    - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? ________

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
    - (a) Physicians 0
    - (b) Laboratory Scientists (PhDs) 0
    - (c) Nurses 2
    - (d) Embryo Lab Technicians/Technologists ________
    - (e) Other Lab Technicians/Technologists 2
    - (f) Radiology (Ultrasound) Technicians 1
    - (g) Psychologists/Counselors ________
    - (h) Secretaries 1
    - (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 2 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF ________ GIFT 10/86

9. How many different patients were stimulated?
1987 IVF ______ 1988 IVF ______
GIFT 13 GIFT 7

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF ______
GIFT about 20 GIFT about 12

Our records are for GIFT stimulations that actually made it to surgery. Number of stimulations I've just estimated.

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 ______ 1988 ______

How many embryo transfer cycles were performed?
1987 ______ 1988 ______

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 11 1988 7

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 0 ___% GIFT 1 14.29%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 3 23.08% GIFT 2 28.5%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 2 15.38% GIFT 3 42.8%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 8 61.54% GIFT 0 ___%
(e) Other (explain): ______________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT 1 14.29% ovulatory dysfunction

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 6 46.15% GIFT 5 71.43%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 5 38.46% GIFT 2 28.57%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 1 7.69 % GIFT 0 ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 1 7.69 % GIFT 0 ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 0 ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF ____ 1988 IVF ____
GIFT ____ GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ____ 1988 IVF ____
GIFT 2 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ____ 1988 IVF ____
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF ____ 1988 IVF ____
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ____________________
GIFT ___ ___% 2 sets of twins

1988 IVF ___ ___% ____________________
GIFT 0 ___% ____________________

21. What are the qualifications of the director of the embryo laboratory? two technicians have been trained to identify ova, isolate ova, load catheter with ova & sperm

22. Who supervises the laboratory director? ____________________

23. Does the clinic participate in an external laboratory proficiency testing program? ____________________
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? _____

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ________
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Ft. Worth Infertility Center
ADDRESS: 1325 Pennsylvania Ave. Suite 750
Ft. Worth, Texas 76104

CONTACT PERSON: Amy Hardgrove, R.N.
PHONE NUMBER: 817-335-0909

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the never clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11-22-88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
    - (a) Private x
    - (b) Community hospital based ________
    - (c) University based ________
    - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
    - (a) Physicians Embryologist
    - (b) Laboratory Scientists (PhDs) ________
    - (c) Nurses 1
    - (d) Embryo Lab Technicians/Technologists 2
    - (e) Other Lab Technicians/Technologists ________
    - (f) Radiology (Ultrasound) Technicians ________
    - (g) Psychologists/Counselors ________
    - (h) Secretaries 1
    - (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 3yrs 7 mos

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 4-2-85 GIFT 9-12-86

9. How many different patients were stimulated?
1987 IVF 32 1988 IVF 30
GIFT 8 GIFT 7

10. How many stimulation cycles were performed?
1987 IVF 66 1988 IVF 85
GIFT 5 GIFT 7

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 31 1988 37

How many embryo transfer cycles were performed?
1987 24 1988 36

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 5 1988 7

13. What were the number and percentage of patients on IRB approved research protocols?
1987 NA ___% 1988 NA ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 20 55% 1988 IVF 20 70%
GIFT 0 ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF 8 35% 1988 IVF 5 15%
GIFT 7 98% GIFT 7 100%
(c) Male infertility:
1987 IVF 11 10% 1988 IVF 3 10%
GIFT 1 1% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF 11 10% 1988 IVF 2 5%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ______________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 27 52% 1988 IVF 38 53%
GIFT 3 35% GIFT 5 80%
(b) 31-35:
1987 IVF 12 23% 1988 IVF 18 25%
GIFT 1 20% GIFT 1 10%
(c) 36-40:
1987 IVF 11 21% 1988 IVF 12 16%
GIFT 4 45% GIFT 1 10%

(d) 41-45:
1987 IVF 2 3 % 1988 IVF 3 4 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 5 ____ % 1988 IVF 2 ____ %
GIFT 3 ____ % GIFT 1 ____ %

16. How many clinical pregnancies were produced?
1987 IVF 5 1988 IVF 2
GIFT 3 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 2 1988 IVF 1
GIFT 0 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ____ % ____
GIFT 0 ____ % ____

1988 IVF 1 ____ % twins
GIFT 0 ____ % ____

21. What are the qualifications of the director of the embryo laboratory? M D & Embryologist

22. Who supervises the laboratory director? The Four physicians

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? We do not have an endocrinologist, therefore we do not meet the criteria for membership, at this time.
27. Does the clinic train individuals in IVF or GIFT? no
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

TEXAS
FERTILITY
CENTER
4th Floor, HCA Medical Plaza Hospital, 1612 W. Humbolt, Fort Worth, TX 76104, 817-336-GIFT

March 9, 1989

Congressman Ron Wyden, Democrat
Chairman Subcommittee on Business Opportunities and Energy
Sam Rayburn House Building
B-363 Washington, D.C. 20515

Attn: Steve Jenning

Dear Congressman Wyden:

Reference is made to the recent article (March, 1989) issue of Time Magazine concerning your investigation of infertility centers throughout the United States. Regrettably, our center, the Texas Fertility Center, Fort Worth, Texas was not included in your data. Mr. Steve Jenning, Staff Director, was very accommodating to me recently via the telephone regarding this study, and at his request, I am enclosing some information on the Texas Fertility Center of Fort Worth, Texas. This center should not be included or confused with another infertility center also located in Fort Worth.

The data that I am enclosing will substantiate the progress that we have made here at TFC and we certainly hope to be included within your data. We would welcome any additional inquiry or investigation into our operation here, and I think our record speaks for itself.

Thank you for the opportunity of allowing us to submit this data and please let us know if there is any additional information you might need in that our record has been good and we feel that we are providing the community a service in this area.

Sincerely,

David M Wooldridge

David M. Wooldridge, M.Ed.
Director of Marketing

cc: J.P. McWherter, M.D.

Enclosures

Helping Couples Become Families

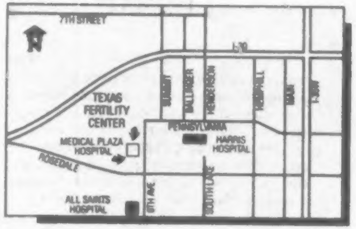
A convenient location, with a team of trained physicians, nurses, counselors, andrologists, an embryologist and gamete physiologist makes it possible, after full treatment, for many couples to look forward to hearing the good news – that she is pregnant!

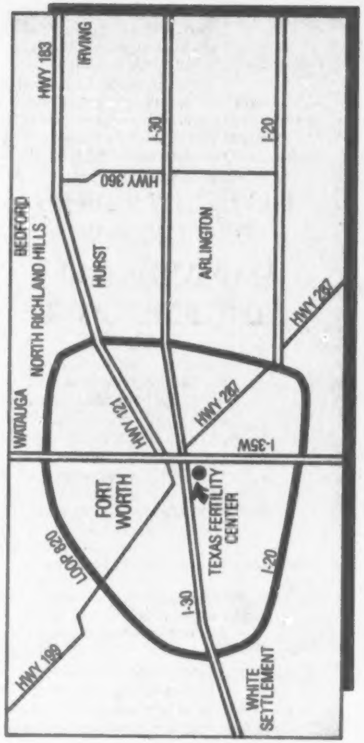
We at TEXAS FERTILITY CENTER are dedicated to Helping Couples Become Families!

To learn more about the services we offer, please contact:

TEXAS
FERTILITY
CENTER

TEXAS FERTILITY CENTER
HCA Medical Plaza, 4th Floor
1612 West Humbolt
Fort Worth, Texas 76104
(817) 336-GIFT


7TH STREET
I-30
SUMMIT
BALLINGER
HENDERSON
HEMPHILL
MAIN
I-35W
TEXAS FERTILITY CENTER
PENNSYLVANIA
MEDICAL PLAZA HOSPITAL
HARRIS HOSPITAL
ROSEDALE
ALL SAINTS HOSPITAL
8TH AVE
SOUTH LAKE


HWY 183
IRVING
I-30
I-20
HWY 360
BEDFORD
NORTH RICHLAND HILLS
HURST
ARLINGTON
HWY 287
WATAUGA
HWY 121
I-35W
FORT WORTH
TEXAS FERTILITY CENTER
LOOP 820
I-20
I-30
HWY 199
WHITE SETTLEMENT

IN VITRO FERTILIZATION PROGRAM

TEXAS
FERTILITY
CENTER

HELPING COUPLES BECOME FAMILIES

HELPING COUPLES BECOME FAMILIES

TEXAS FERTILITY CENTER offers specialized fertility treatment with proven up-to-date avenues for achieving pregnancy. The Center offers couples basic infertility evaluations, sophisticated In Vitro Fertilization Embryo Transfer (IVFET), or Gamete Intra-fallopian Transfer (GIFT).

A team of experienced, caring physicians, scientists, nurses, counselors and technicians has been assembled to provide the expert care you deserve. Successes in both IVFET and GIFT have been enjoyed by a team of physicians with a special interest in infertility. The Center's physicians have been trained in successful IVF programs in Australia, Canada, and the United States.

IVF/GIFT

In vitro literally means "in glass" and indicates that fertilization, which involves the husband's sperm and the wife's eggs, takes place in a laboratory dish rather than in her body. IVFET thus refers to fertilization of the egg (ovum) outside of the body, IVF, and the subsequent transfer of the fertilized egg (embryo) back into the uterus, ET.

To accomplish IVFET, the ovaries are hormonally stimulated in order to recruit many eggs during the cycle. The eggs are then retrieved using a laparoscope, or vaginal ultrasound probe (requiring local anesthesia only). In a special laboratory the eggs are then fertilized with the partner's sperm and resulting embryos are transferred approximately two days later into the uterus. Implantation of the embryo to the uterus must occur if pregnancy is to result.

For many couples, GIFT is used to achieve pregnancy. Unlike IVFET, this technique involves placing the couple's gametes (eggs and sperm) into the wife's own fallopian tube(s). Here fertilization occurs in the natural environment of the body. The wife must have at least one healthy tube for GIFT.

During the evaluation and consultation process, each couple will be assessed as to the advisability of IVF and/or GIFT.

Conditions currently applicable to IVFET include:

- Untreatable tubal occlusion
- Failure to conceive following tubal surgery, when additional surgery is not feasible
- Failure to conceive after treatment for endometriosis
- Unexplained infertility
- Male factor (poor sperm count or function)
- Cervical factor

Certain infertility couples, i.e. patent fallopian tube(s), may benefit by GIFT. Conditions treated by GIFT include:

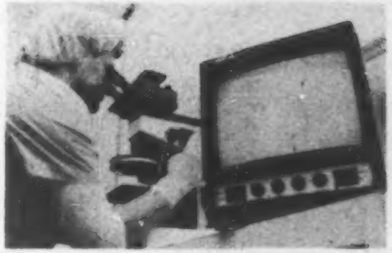
- Solitary male factor
- Unexplained infertility
- Endometriosis

BASIC INFERTILITY INVESTIGATIONS

IN ADDITION TO SOPHISTICATED IVF/GIFT

In general, most couples will conceive after one year of random, unprotected intercourse, or after six months of timed sexual contact. A thorough fertility examination at the Texas Fertility Center includes:

- careful history and physical examination
- evaluation of ovarian function
- cervical factor analysis
- uterine and tubal integrity
- pelvic laparoscopy



TEXAS FERTILITY CENTER PROVIDES:

- A unique concept in that all procedures and studies are performed in one convenient location (4th Floor, HCA Medical Plaza Hospital);
- State-of-the-art operating facilities for laser and reproductive surgery;
- A special laboratory open seven days a week to provide endocrine tests, cryopreservation, sperm evaluation and processing (sex selection). Here it is possible to achieve enhancement of sperm counts and/or motility;
- The expert support of an andrologist and urologists to resolve male factor infertility;
- Artificial insemination (meeting AFS standards) for specific infertility problems;
- Ovarian evaluation and egg retrieval, making use of ultrasound and employing appropriate ovarian stimulation protocols (Lupron, Clomid, Pergonal, Metrodin);
- Complete IVF and GIFT facilities;
- Evaluation of couples who suffer habitual miscarriages;
- Psychological support and counseling.

TEXAS
FERTILITY
CENTER
4th Floor, HCA Medical Plaza Hospital, 1612 W. Humbolt, Fort Worth, TX 76104, 817-336-GIFT

December 20, 1988

The Texas Fertility Center's IVF and andrology laboratories were completed this September. The first formal IVF cycle using the completed facilities began in mid-October and we would like to report the following: Out of 10 patients who underwent standard IVF stimulation protocols and had at least two embryos transferred, four became pregnant, resulting in a 40% pregnancy/transfer rate. One patient, not included in the above, had only one embryo transferred and did not become pregnant.

A total of 95 eggs were obtained from these patients using both ultrasound and laparoscopic techniques with an 88% fertilization rate.

One of the four pregnancies resulted using zygote intrafallopian transfer(ZIFT), and is the first successful ZIFT in Tarrant County.

We appreciate your support and look forward to continued successes in IVF cycles.

Best Wishes,

Texas Fertility Center

TEXAS
FERTILITY
CENTER

4th Floor, HCA Medical Plaza Hospital, 1612 W. Humbolt, Fort Worth, TX 76104, 817-336-GIFT

Dear Doctor:

We are proud to announce that the Texas Fertility Center has the ability to offer you and your patients the special services required in the resolution of infertility.

Our facilities, located on the 4th Floor of the HCA Medical Plaza Hospital, can offer your patients quiet, friendly and very private accomodations: including waiting room and reception area; managerial office where all financial arrangements can be discussed in private; physician and nurse's office for private interviews and examination rooms.

Texas Fertility Center provides complete infertility treatment which includes a full service endocrine and andrology laboratory. We stress rigid quality control rather than high volume business. As an example, a semen analysis is performed by the andrologist using a broad battery of tests employed by many major IVF centers We feel the need for this commitment of time and expertise as male factor infertility assumes a dominant role in patient treatment.

Our support personnel is highly qualified and trained in every step of the patient's care with special emphasis toward couples with such a sensitive and disturbing problem as infertility. Psychological counselling and group counselling will be made available for those who feel that they require special management of their problem.

You are encouraged to make use of the facilities at Texas Fertility Center. The nurse coordinator is experienced in the care of the infertility patient while the laboratory director, trained in both embryology and genetics, specializes in male infertility.

Also, Texas Fertility Center includes a successful IVF/GIFT laboratory staffed by an experienced gamete physiologist. We encourage you to make use of this facility and our support personnel will assist you if needed.

Our staff is available 7 days a week by appointment. We will be happy to answer all your questions. You can contact us by calling 336-GIFT.

Sincerely,

Janina Michalowska, Ph.D.
Laboratory Director

Helping Couples Become Families

TEXAS FERTILITY CENTER

Fertility Investigation

Schematics are included in the PROCEDURES section of this manual which are designed to illustrate how Texas Fertility Laboratories and Center may assist you in the fertility investigation. A fertility investigation requires a seven day a week commitment of time. The Center is designed with this in mind, thus helping the physician use his time efficiently. Using both the laboratory and the Center, the physician may treat the patient as far as his or her skill permit. The schematics are not designed to suggest how the physician should institute the fertility work up.

Some couples will not respond to routine fertility treatment and may be candidates for IVF-ET and/or GIFT. Since the Texas Fertility Center is based upon physician participation, one is encouraged to take a active role in this process if he or she so desires. If not, the Center can provide the required professional treatment and return the patient to the referrring physician.

An estimation of prices for IVF-ET and GIFT has been provided. Every attempt has been made to curb costs yet ensure the highest quality of care. Your support of the Texas Fertility Laboratory will help in this effort.

The Center and Laboratory personnel would appreciate any suggestions as to how services can be improved and what laboratory tests should be made available.

SERVICES AND POLICIES

COURIER SERVICE: Routine courier service will be provided for certain specified specimens (Hormones and Chromosome studies) twice per day at 9:00 a.m. and 4:00 p.m. There will be a transportation charge for pickups other than those scheduled.

SPECIMEN COLLECTION FROM PATIENTS AT LABORATORY: Patients may be sent to our laboratory, located on the 4th Floor of Medical Plaza Hospital, 1612 W. Humbolt, Ft. Worth, Texas. Our facility is open for patient specimen collection from 8:30 a.m. to 4:30 p.m. Monday through Friday and BY APPOINTMENT on weekends and holidays. There is an additional fee for any test done after hours, weekends or holidays.

REQUEST FORMS: Preprinted request forms, designed to simplify ordering, are supplied. The laboratory requires that a request form accompany each specimen submitted. Pertinent information such as date and time of specimen collection, age and sex should be included on the request form. See "Instructions" for specific tests.

SUPPLIES: If needed, the proper supplies for collection will be supplied by us.

REFERRED TESTS: Certain laboratory procedures may be referred to another laboratory. Since these laboratories may alter their fees, the fees for these tests listed in our fee schedule are subject to change without notice.

BILLING PROCEDURE: The physician has the option of billing the patient directly or through his office. Discounts for charges billed through the physician's office will be arranged. The exact percentages are based on volume.

Arrangements can be made for patients to have laboratory tests or specific procedures performed by calling 336-GIFT.

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Fourth Floor, MEDICAL PLAZA HOSPITAL
1612 West Humbolt
Fort Worth, Texas 76104
817-336-GIFT

Dear Physicians:

The following schedule of laboratory fees are those which are charged the patients at the Texas Fertility Center.

Physicians' fees will be adjusted according to volume and other factors. We will be happy to bill the patient, or your office may wish to do this.

Please feel free to call our lab for any additional information concerning the particulars of any test or our quantity discounts.

Thanks!

LABORATORY FEE SCHEDULE

ANDROLOGY

	Patient Charge	Physician Charge
Semen Analysis: Analysis includes the estimation of volume, pH, and viscosity of the seminal fluid in addition to sperm concentration and motility. If abnormal motility or absence of sperm is noted, an Eosin Y stain and/or Fructose test is performed. Morphology assessment is based on Kruger's parameters.	$75.00	$40.00
Semen Analysis (Post vasectomy): Seminal fluid is centrifuged (2000 rpm) to form a cell pellet which will be assessed for the presence or absence of sperm cells.	45.00	35.00
IUI Sperm Preparation: Sperm is prepared for intrauterine insemination by washing, incubating, then separation of the motile fraction with swim up techniques. The media used for this process is supplemented with the wife's serum which is a source of proteins needed for capacitation of sperm.	90.00	60.00
IUI Sperm Preparation w/ Capacitation: Sperm is incubated with TEST Egg Yolk Buffer for approximately 20 hours; then, the sperm is washed and processed with the swim up technique listed above. This will enhance sperm capacitation and fertilization capability. We recommend this for artificial insemination involving couples with male factor.	100.00	75.00
Preparation of Donor Serum for IUI Sperm: If the wife's serum has antisperm antibodies, donor serum is used to supplement media for IUI sperm preparation.	50.00	40.00
HEPA (**Hamster Egg Penetration Assay**): Performed by incubation of the husband's sperm with zona pellucida free hamster eggs. This will test the capability of the sperm to fertilize the wife's oocytes.	350.00	350.00
Huhner (**Post Coital**) **Test**: The embryologist examines the cervical mucous for sperm number and motility. This can rule out cervical factor infertility or indicate the need for antisperm antibody test.	50.00	25.00
Sex Preselection: Special techniques are used to separate X or Y bearing sperm.	400.00	360.00
Antisperm Antibodies: Both husband and wife can be tested for antisperm antibodies (IgG or IgA) in serum, sperm, seminal fluid, or cervical mucous.	100.00	85.00
Husband Sperm Cryopreservation: The husband's sperm is cryopreserved and stored in liquid nitrogen. This procedure is recommended if he is not available for insemination or in vitro fertilization of the wife's oocytes.	75.00	50.00

	Patient Charge	Physician Charge
Cervical Mucous Penetration: Bovine cervical mucous is used to assess the sperm's ability to penetrate cervical mucous.	$50.00	$40.00
Donor Sperm: Two vials of frozen donor sperm, chosen by the couple, are obtained from a commercial sperm bank which meets AFS standards. The vials are stored in nitrogen tanks and subsequently prepared for IUI or cervical insemination.	350.00	350.00

HORMONES

LH	45.00	25.00
FSH	45.00	25.00
Prolactin	45.00	25.00
Testosterone	45.00	25.00
DHEA	45.00	25.00
TSH	45.00	25.00
T3	45.00	25.00
T4	45.00	25.00
hCG: Quantitative (Serum)	45.00	30.00
Qualitative (Urine)	18.00	10.00
E2	55.00	30.00
Progesterone	55.00	30.00
Stat Charge		20.00

Hormones: RIA or EIA (Radioactive immuno assay or Enzymatic immuno assay) methods are used to obtain hormone values which are critical for evaluation and treatment of a couple's fertility problem. Since ovulation protocols are based on precise values (especially estradiol E2), results are available within 3 hours.

CHROMOSOME STUDIES

Chromosome Studies: Amniotic fluid cell(amniocytes) chromosome studies can rule out rearrangements or changes in chromosome number.	450.00	
Blood Chromosome Studies: Chromosome studies are performed on stimulated blood leukocytes to determine the possible cause of fetal malformations, hematological disorders, or infertility problems.	350.00	
Tissue Chromosome Studies: These studies rule out chromosomal abnormalities which may cause habitual abortion. Tissue of fetal origin (chorionic villi, skin, kidney, or gonadal) is used for chromosomal study. In adults, skin or ovarian biopsy samples can be studied for mosaicism or sex chromosome syndromes.	450.00	

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HLA Typing: Human lymphocyte antigen typing is performed in cases of recurrent abortions where abnormal immune response is suspected. Loci which are of interest are DR and DQ.	400.00

Explanations for each of the above tests are provided in detail in thes manual under "Description of Tests" and "Specimen Requirements".

IVF/GIFT

IN VITRO FERTILIZATION AND GAMETE INTRA-FALLOPIAN TRANSFER

The cost for one cycle of In Vitro Fertilization (IVF) and Gamete Intra-fallopian Transfer (GIFT) are as follows. There may be variations in the amount of medication necessary for the treatment and this may vary the total cost. Therefore, the range of usual costs for several steps is given and noted in parenthesis. These fees do not include hospital or anesthesia charges.

I. Ovulation Induction:

Antisperm Antibodies ($100.00 per patient)		200.00
Rubella		15.00
Semen Analysis		75.00
Hepatitis (Husband & Wife $42.80 each)		85.60
HIV (Husband & Wife $30.00 each)		60.00
Estradiol	$55.00 per sample	350.00-450.00
LH	$45.00 per sample	225.00
FSH	$45.00 per sample	45.00
Pergonal	$40.00 per ampule (Cost will depend upon the stimulation)	800.00-1200.00
Clomid	Prescription cost may vary	
Lupron		400.00
HCG	10,000 Units (+/-)	130.00
Sonography (Technical and interpretation)		200.00
Professional Consult. fee for ovulation monitoring		200.00

II. Laboratory Fees:

IVF Embryo Culture	900.00
GIFT Processing	750.00
Combination IVF/GIFT	900.00
Laparoscopy-Follicular Aspiration:	
Physician's Professional Fee	1000.00
Embryo Transfer (IVF only):	
Laboratory fee	200.00
Physician's Transfer fee	100.00
Other:	
Progesterone injections	12.50
Serum Pregnancy Test	45.00

TOTALS: GIFT $1750.00 + Progesterone Injections
IVF 2200.00 " "
Combo 2200.00 " "

GENERAL STUDIES

The following studies are sent to a reference laboratory and the fees are subject to change.

HIV	$ 23.75
Rubella	15.00
Hepatitis	43.00
Chlamydia	150.00
RPR	15.00
CMV	90.00
AFP	45.00

DISCOUNTS FOR CHARGES BILLED THROUGH THE PHYSICIAN'S OFFICE WILL BE ARRANGED. THE EXACT PERCENTAGES ARE BASED ON VOLUME AS IS STANDARD PRACTICE.

AFTER HOURS: THERE WILL BE AN ADDITIONAL CHARGE FOR ANY LABORATORY TESTS PERFORMED AFTER ROUTINE LABORATORY HOURS IN ADDITION TO A TRANSPORTATION CHARGE FOR COURIER PICK-UPS OTHER THAN ROUTINE SCHEDULED PICK-UPS.

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MONDAY

Semen Analysis
Intrauterine Insemination
Postcoital Test
Sex Preselection (by appointment)
Sperm Cryopreservation
Cervical mucus penetration
Chromosome studies

ENDOCRINE EVALUATION:
E2
LH
Progesterone
Testosterone
hCG (quantitative)
HLA-typing-results in 3 days

TUESDAY

Semen Analysis
Intrauterine Insemination
Postcoital Test
Sex Preselection (by appointment)
Cervical mucus penetration
Chromosome studies
Hamster egg penetration test (by appointment) **SPECIMEN DUE DUE MONDAY

ENDOCRINE EVALUATION:
E2
LH
FSH
DHEAS
T3, T4
HLA typing-results in 3 days
hCG (quantitative)

WEDNESDAY

Semen Analysis
Intrauterine Insemination
Postcoital test
Sperm Cryopreservation
Cervical mucus penetration
Sex Preselection (by appointment)
Antisperm Antibodies(by appointment)

ENDOCRINE EVALUATION:
E2
Progesterone
LH
Prolactin
hCG (quantitative)
HLA typing-results in 3 days

THURSDAY

Semen Analysis
Intrauterine Insemination
Postcoital test
Sex Preselection (by appointment)
Sperm Cryopreservation
Cervical mucus penetration
Antisperm antibodies (by appointment)

ENDOCRINE EVALUATION:
E2
FSH
LH
TSH
T3,T4
hCG (quantitative)

FRIDAY

Semen Analysis
Intrauterine Insemination
Postcoital test
Sex preselection (by appointment)
Sperm cryopreservation
Cervical mucus penetration
AFP

ENDOCRINE EVALUATION:
E2
Progesterone
LH
Prolactin
Testosterone
hCG (quantitative)

SATURDAY/SUNDAY: E2 and LH on special request
hCG (quantitative)
Sperm preparation for intrauterine insemination
Sex preselection

MONDAY THROUGH FRIDAY: HIV, Hepatitis, Chlamydia, Rubella, CMV

SPECIMEN DELIVERED BEFORE 9:00 a.m. WILL BE TESTED THE SAME DAY AND THE RESULTS WILL BE AVAILABLE THE FOLLOWING DAY.

LABORATORY TESTS AVAILABLE

ANDROLOGY

Semen Analysis

Semen Analysis (post vasectomy)

IUI Sperm Preparation

IUI Sperm Preparation with Capacitation

IUI Serum Preparation (Donor)

HEPA (Hamster Eggs Penetration Assay)

Huhner (Post Coital) Test

Sex Preselection

Antisperm Antibodies Test

Husband Sperm Cryopreservation

Cervical Mucus Penetration

Donor Sperm from Sperm Bank

HORMONES:

LH

FSH

Prolactin

Testosterone

DHEA

TSH

T3

T4

hCG - Quantitative (Serum)
hCG - Qualitative (Urine)

E2

Progesterone

GENERAL:

HIV

Hepatitis

Chlamydia

Rubella

CMV

AFP

RPR

CHROMOSOME STUDIES

Blood

Amniotic Fluid

Tissue

HLA TYPING

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SEMEN ANALYSIS

An objective evaluation of the semen provides important information as to the functional competence of sperm cells and the contribution of the male to the couple's infertility.

Proper interpretation of the semen parameters is possible only when the factors which can lead to artifactual results are recognized and observed by the physician, office personnel and patients.

The necessary factors include:

1) SPERM COLLECTION

It is necessary for all patients to collect the semen specimen by masturbation into a clean, sterile container provided by the physician's office or by Texas Fertility Center. Texas Fertility Center provides a room for specimen collection with a direct pass-through to the laboratory. Patients who are unable to collect a specimen at Texas Fertility Center are asked to bring a sample to the laboratory within one-half hour.

2) SEXUAL ABSTINANCE

The period of sexual abstinance has a very significant effect on semen quality. For optimal results, an abstinance of not LESS than 48 hours and no MORE than 72 hours is required before the semen evaluation.

3) SPECIMEN TRANSPORTATION

The method of transportation of the semen may have an important bearing on the test results. During transportation, the semen must not be exposed to extremes of temperature and should be maintained at body temperature, i.e., carrying the container in an inside pocket.

Semen analysis is available Monday through Friday between the hours of 8:30 a.m. and 4:00 p.m. Results will be available the following day or can be called to the referring physician on the same day.

PLEASE REFER TO INSTRUCTIONS FOR FULL EXPLANATION OF SPECIMEN COLLECTION.

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1612 West Humbolt
Fort Worth, Texas 76104
817-336-GIFT

SPERM ANALYSIS

Patient Name____

Referring Physician____________________________ Lab #__________

Date of Collection____________________________

Abstinance (days)____________________________

Macroscopic Observation:		Normal Range
volume		1.5-6.0 mls
pH		7.4-8.0
color		opaque
viscosity		reduced after 20 min
clumps		not determined
Microscopic Observation:		
sperm concentration (10^6/ml)		20-350x10^6/ml
total sperm count (10^6/total volume)		
motile spermatozoa (%)		>50%
progressive motility		
agglutination (%)		≥10%
Morphology:		
normal spermatozoa (%)		≥60%
abnormal heads (%)		
abnormal midpieces (%)		
abnormal tails (%)		
Mononuclear Cells:		
immature cells		normals not determined
leukocytes		4.7x10^6/ml.
epithelial cells		normals not determined

Interpretation______________________________

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Comments__________________________________

Date________________________

Janina Michalowska, Ph.D
Laboratory Director

HUSBAND SPERM CRYOPRESERVATION

Texas Fertility Center offers semen cryopreservation and storage for couples when the husband's absence is expected or when his business travel is frequent and may preclude his presence near the time of the wife's ovulation.

Cryopreservation results in a loss of 60-70% motility of the sperm; therefore, it is not recommended for patients with a low sperm count or poor motility.

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SPERM PROCESSING FOR INTRAUTERINE INSEMINATION

The value of intrauterine insemination for the treatment of infertility has been established. The most frequent indication is a male factor infertility (oligospermia, ejaculatory difficulties, low motility, low semen volume). IUI has been used also in cases of immunological infertility as well as in cases of unexplained infertility.

Artificial insemination with homologous (husband's) sperm can be performed by introducing into the uterus 0.5 ml. of the sperm suspension in a medium enriched with proteins. For males with a low sperm count, concentration of the sperm by collecting two specimens in 24-48 hour intervals is available.

Texas Fertility Center requests that the husband collect the specimen to be used for IUI approximately 3 hours before insemination time. The specimen should be collected at Texas Fertility Center. At the same time, 10 ml. of the wife's blood will be collected. The blood serum is used as a source of proteins, unless specified differently by the referring physician or laboratory director.

The husband must abstain from sexual activity for no less than 48 hours and no more than 72 hours.

Texas Fertility Center offers semen cryopreservation and storage for families when the husband's business travel is frequent and may preclude his presence near the time of the wife's ovulatory time. The referring physician is welcome to use our examination rooms for insemination, or the patient can take a prepared specimen to the physician's office. We will provide the package for transportation.

DONOR SPERM FROM SPERM BANK IS AVAILABLE FOR INSEMINATION. The sperm bank has screened the donor's genetic background carefully. The donor has been tested for communicable and veneral diseases prior to collecting the specimen. The sperm is frozen and the donor is tested again in 6 months. If he is still negative for diseases, the frozen sperm is then available for use for artificial insemination. The donor list is available by contacting Texas Fertility Center.

Texas Fertility Center is open for this procedures 7 days a week from 8:30 a.m. to 4:00 p.m. However, we will appreciate receiving the specimen no later than 1:00 p.m. to allow for the 3 hour processing. Please call to schedule this procedure one day prior, or on Friday for Saturday or Sunday processing.

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HAMSTER EGG PENETRATION ASSAY (HEPA)

In approximately 50% of couples with fertility problems, male factors are etiologic. Male infertility has multiple causes and varying efforts have been devoted to establish laboratory tests able to measure functional properties of human sperm.

In has become obvious that the functional competence of the spermatozoa is not reflected by results obtained in the conventional semen analysis. The human-hamster system is an assay which permits evaluation of the ability of human sperm to capacitate, to undergo the acrosome reaction and to fuse with the vitelline membrane of the oocyte. The fusion of the sperm head with zona free hamster egg indicate that sperm capacitated and the acrosome reaction occurred.

The results of the sperm/egg interaction are reported as a percentage of the penetrated eggs and SCI (Sperm Capacitation Index) which is a mean of the number of the enlarged sperm heads counted per ovum. SCI (Sperm Capacitation Index) has been shown to be more sensitive than a percentage of the penetrated eggs. Certain infertile patients can achieve positive penetration scores, but their SCI will be very low. When using these two parameters, hamster egg penetration test correlates with ovum fertilization rates in IVF programs.

The information obtained by the HEPA should be used in assessing and monitoring of treatment of the male factor (after varicocele repair, pregnancy occurred when HEPA results improved into the fertile range).

It needs to be stressed that HEPA does not reproduce in one hundred percent (100%) in vivo conditions. It gives an evaluation of the male potential and should be used to monitor special treatments.

Texas Fertility Center laboratory has this test available Tuesday by appointment only. To schedule patients, please call 817-336-GIFT.

Results will be reported to the referring physician the following day.

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EVALUATION OF HAMSTER EGG PENETRATION ASSAY

PATIENT NAME_____________________________________DATE_______________

REFERRING PHYSICIAN____________________________________LAB #________

	Total # of analyzed eggs	Number (%) of penetrated eggs	SCI
Patient			
Donor			

Interpretation:____

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Date____________________

Janina Michalowska, Ph.D
Laboratory Director

POSTCOITAL TESTING

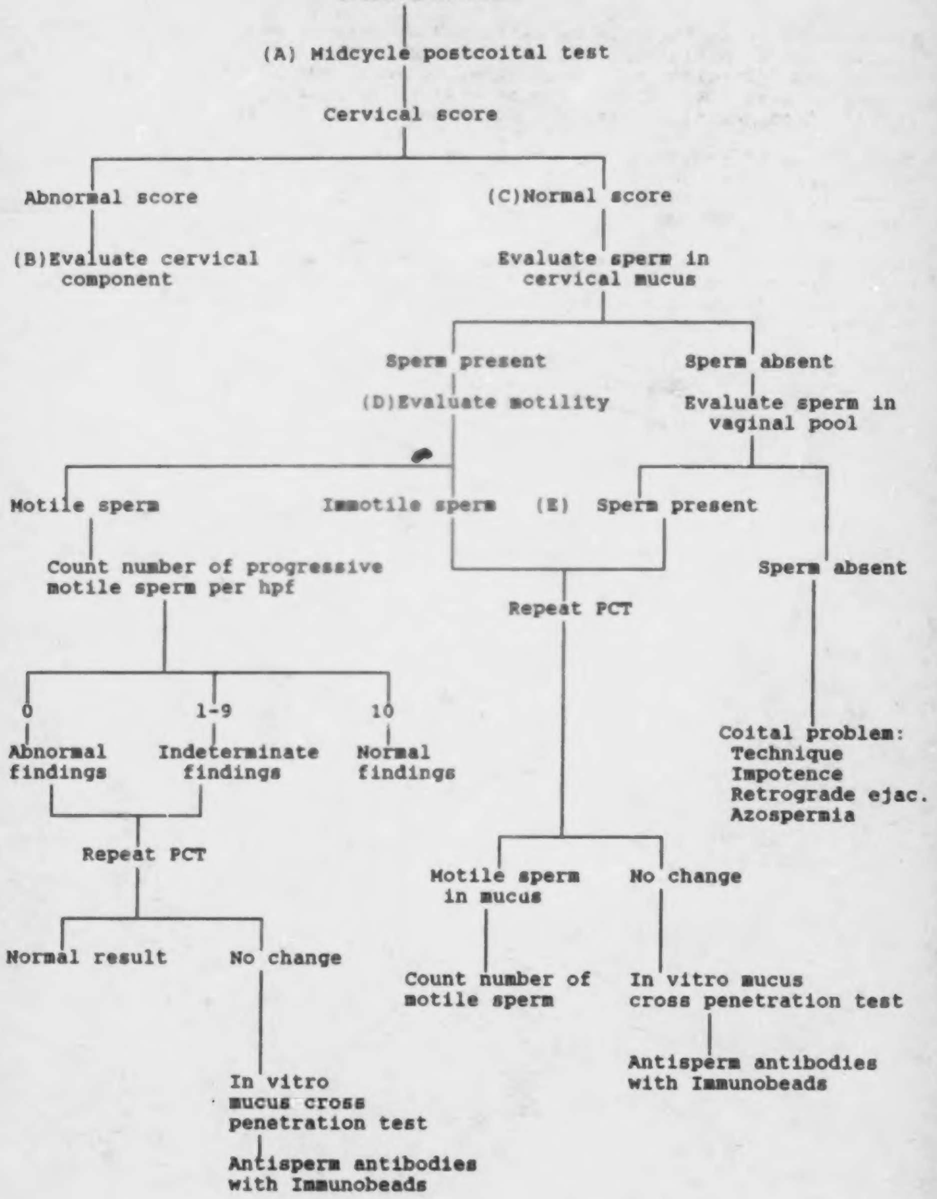
The postcoital test should be performed as near as possible to the time of ovulation. You may use basal body temperature, cervical mucous changes, hormonal assays or an ovulation test kit. The couple should be instructed to abstain from sexual intercourse for 2 days prior to the test.

The morning of the test, the couple should be instructed to have sexual intercourse and then report to the office for the postcoital test within 2-6 hours or as deemed by the physician.

The presence in the endocervix of an adequate number of motile spermatozoa suggests a favorable mucous and adequate survival of sperm in the cervix; it excludes cervical factors as a cause of infertility.

Texas Fertility Center is equipped to perform this test 7 days a week. If you plan to have this test completed on the weekend, please make arrangements with Texas Fertility Center by Friday of that week.

ADMINISTRATION OF POSTCOITAL TEST: SPERM COMPONENT


(A) Midcycle postcoital test
Cervical score
Abnormal score
(B) Evaluate cervical component
(C) Normal score
Evaluate sperm in cervical mucus
Sperm present
(D) Evaluate motility
Sperm absent
Evaluate sperm in vaginal pool
Motile sperm
Immotile sperm
(E) Sperm present
Sperm absent
Count number of progressive motile sperm per hpf
Repeat PCT
0
1-9
10
Abnormal findings
Indeterminate findings
Normal findings
Coital problem:
Technique
Impotence
Retrograde ejac.
Azospermia
Repeat PCT
Motile sperm in mucus
No change
Normal result
No change
Count number of motile sperm
In vitro mucus cross penetration test
Antisperm antibodies with Immunobeads
In vitro mucus cross penetration test
Antisperm antibodies with Immunobeads

SPERM PREPARATION FOR SEX PRESELECTION

Several scientifically based methods have been advanced in recent years to preselect the gender of the offspring.

The fundamental difference between sperm is a presence of either an X or a Y chromosome. Research involving sex preselection focuses directly or indirectly upon this essential characteristic.

At present, clinically used methods are based on either discontinuance albumin gradient, yielding a highly motile population to be enriched for Y bearing cells, or gell filtration methods to collect fraction rich in X bearing sperm.

By using these techniques for sex preselection, we are able to increase the chances of having a baby of the desired sex to 75%.

Texas Fertility Center Laboratory is offering this procedure for patients who are in higher risk for X-linked diseases or for patients who would like to choose the sex of their child.

Patients interested in this procedure are welcome to call us for an appointment Monday through Friday between the hours of 8:30 a.m. and 5:00 p.m. Weekend and holiday appointments are available if arranged during normal working hours.

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ANTISPERM ANTIBODIES TESTING WITH IMMUNOBEADS

Antisperm antibodies are clinically significant because of their association with infertility in both the male and female. It has been demonstrated that various sperm antigens can stimulate the production of antisperm antibodies. As a result of chemical or physical trauma or infection, the blood-testis barrier in the male can break down and expose the male immune system to sperm antigen, resulting in the production of antibodies. This can frequently happen after vasectomy.

The female reproductive tract is not protected by any special barrier system. Spermatozoa, which are immunologically foreign to the female, usually do not stimulate humoral immune response. Immunosuppressive factors present in seminal plasma are probably preventing the formation of antibodies. However, in some cases, continuous exposure to sperm can result in antisperm antibody production which impairs fertility. Sperm agglutination, lack of fertilization, impaired cervical mucus penetration and pre or post implantation embryo loss are results of the antisperm antibody formation.

Antisperm antibodies can be detected in both the female and male partner using direct (sperm) or indirect (serum, seminal plasma or cervical mucus) using immunobeads testing technique. Both localization of antisperm antibodies on the sperm cell (binding to sperm head, midpiece or tail) and percentage of sperm affected are very significant for fertility diagnosis and treatment.

Texas Fertility Center laboratory offers antisperm antibodies testing Wednesday and Thursday morning by appointment. A fresh semen specimen should be collected according to our semen analysis protocol on the day of the test. If the sperm count and motility is insufficient for assay, the patient will be asked for a blood sample. The female's blood can be drawn on the morning of the test day or a few days before since the serum can be frozen.

Results are available the following day and the referring physician will be notified.

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ANTI-SPERM ANTIBODIES

Patient name ______________________________

Referring physician ____________________ Lab # __________

Date of collection blood: ______________ Semen: __________

	direct			indirect	
	% of bound IgG	% of bound IgA		% of bound IgG	% of bound IgA
head			head		
mid-piece			mid-piece		
tail			tail		
tip of tail			tip of tail		
total			total		

Interpretation ______________________________

____

____

Date ______________

Janina Michalowska Ph.D.
Laboratory Director

ALPHAFETOPROTEIN TESTING

Measuring the second trimester concentration of the maternal serum alphafetoprotein (AFP) has been established as a means of identifying pregnant women in the general population who are at high risk of carrying a fetus with certain defects associated with lower than normal or elevated levels of AFP's. An elevated level can indicate a fetus with an open neural tube defect, ventral wall defect or multiple pregnancy. A lower than normal level could suggest a pregnancy with trisomies or fetal death.

Texas Fertility Center will provide AFP testing (maternal and amniotic fluid). Interpretation of the results will be given to the referring physician with adjustment for maternal age, weight, race and insulin dependent diabetes diagnosed prior to pregnancy. Calculation of the risk of having a child with Down syndrome will be presented if results fall below normal range.

An abnormal AFP level result will be immediately called to the referring physician. Gestational age will be calculated taking into account ultrasonography and/or physical examination.

A maternal serum AFP screen schematic and Texas Fertility Center requisition forms are enclosed for AFP testing.

Blood collection and courier service will be arranged with the referring physician on an individual basis.

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DONOR SPERM FOR ARTIFICIAL INSEMINATION

Donor sperm from an AATB (American Association of Tissue Banking) accredited sperm bank is available through Texas Fertility Center. Extensive testing and investigation of the donor is accomplished over a 6 month period before the sperm is available for use in artificial insemination.

A comprehensive family history is taken regarding ethnic background and possible genetic diseases including any history of heart disease, hypertension, diabetes or psychological disorders. Any diseases that run in the family are investigated. Donors are screened for Tay Sach's disease, B Thalassemia and sickle cell anemia. The sperm bank offers chromosome blood studies to exclude the possibility of chromosome rearrangement if required by the patient.

A sperm specimen is accepted for freezing on the basis of count, motility and morphology.

The donor's blood is typed and all donors are tested over a 6 month period for AIDS, CMV, Hepatitis, Herpes, syphilis, Chlamydia, gonorrhea, mycoplasma and ureaplasma. A GC (gonorrhea) culture is taken once a month.

The frozen specimen is released for use only if the donor presents no genetically transmitted diseases and no recurring diseases or disorders in his family history **AND** if he is free of communicable diseases after the 6 month testing period.

The sperm bank assures a count in excess of 20 million of sperm per sample.

The patient chooses the donor from a Donor Profile supplied by Texas Fertility Center. It provides the patient with information regarding the donor's origin, blood type, eye color, hair color and type, complexion, height, body build, years of education and occupation. The patient is asked to pick 3 donors by order of preference. To insure delivery at the optimal time for insemination, Texas Fertility Center prefers to order the specimen 1 week prior to anticipated use. Texas Fertility Center prepares the specimen for intrauterine or cervical insemination dependent upon the physician's request.

To obtain donor semen, have your office call the nurse coordinator (336-GIFT). You may use Texas Fertility Center's facilities for insemination. If you are not available at the time of insemination, arrangements can be made for the patient to be treated at TFC by staff.

ENDOCRINE TESTING

The demand for endocrine investigation and treatment for patients (male and female) with fertility disorders is rapidly growing. The timing and accuracy of these assays are essential for further therapy.

Texas Fertility Center Laboratory is offering assays for LH, FSH, Prolactin, Progesterone, Testosterone, DHEAS, Estradiols, TSH, T3, T4 and hCG-quantitative (sensitive test for pregnancy), based on EIA (enzyme immunoassay) or RIA (radioimmunoassay) techniques. UCG is also offered.

The trained personnel at Texas Fertility Center can assist the physician in both the timing and collection of these tests. This will help the physician maximize his time in patient treatment.

Testing is available 7 days a week (weekend by appointment). Enclosed you will find a protocol for blood collection procedure. The test accuracy will depend on the specific requirements for specimen collection.
PROTOCOL FOR BLOOD COLLECTION:

1) Blood should be drawn in the red top tube without serum separator or with syringe.
2) Each tube must be labeled with the patient name, date and time.
3) Put tube with requisition form specifying all tests requested into plastic bag.
4) Call Texas Fertility Center for courier pick up.
5) Blood collected after 4:00 p.m. should be processed as follows:
    a) let blood clot for 45 minutes.
    b) spin down for 30 minutes at the maximum speed.
    c) remove serum with serological pipet without disturbing red cells and dispense into sterile tube marked with patient's name.
    d) serum frozen

    Serum will be picked up the following morning.

The patient can be sent to Texas Fertility Center for specimen collection or routine courier service will be provided twice per day at 9:00 a.m. and 4:00 p.m. if we are notified of a needed pickup. There will be a transportation charge for pickups other than those scheduled. In most cases, specimens which are spun down according to the protocol can be safely kept in the physician's office until the scheduled routine pick up.

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SPECIMEN COLLECTION REQUIREMENTS

All specimens must be labeled with patient's name, referring physician's name and date. Each specimen must be delivered with a completed Texas Fertility Center requisition form with the test requested clearly marked.

SEMEN ANALYSIS: Available Monday through Friday, 9:00 a.m.-4:00 p.m. Courier service is not available for this test.

1) Sperm collection must follow 48 hours of sexual abstinance but no longer than 72 hours.

2) Specimen must be collected by masturbation in a sterile container. (Sterile containers are available at Texas Fertility Center).

3) Specimen must be delivered to laboratory within 30-45 minutes after collection.

4) If specimen is collected outside of Texas Fertility Center, it must be protected from excessive heat or cold (specimen should be kept at body temperature)

SPERM COLLECTION FOR INTRAUTERINE INSEMINATION (IUI): Available Monday through Friday 8:30 - 4:00. Weekends and holidays by appointment. Courier service is not provided for this test.

1) Sperm collection must follow 48 hours of sexual abstinance but no longer than 72 hours.

2) Specimen must be collected by masturbation in sterile container which are available at Texas Fertility Center.

3) Specimen should be collected at Texas Fertility Center. If collected outside of TFC, the specimen must be protected from exposure to heat or cold. SPECIMEN SHOULD BE KEPT AT BODY TEMPERATURE.

4) Specimen must be delivered within 30-45 minutes following collection and 3 hours before a scheduled IUI.

5) Wife's blood sample must be collected at the same time of the semen specimen deliver unless specified differently by the physician or laboratory director.

SPERM COLLECTION FOR IUI WITH CAPACITATION: Available Monday through Friday 8:30-4:00. Weekends and holidays by appointment. Courier service not available for this test.

1) Requirements for specimen collection are the same as IUI (intrauterine insemination).

2) Collection of the first specimen should be done approximately 24 - 48 hours before the estimated time of IUI.

3) The second specimen should be collected approximate 3 hours before IUI scheduled.

HAMSTER EGG PENETRATION ASSAY (HEPA): Available Tuesday by appointment only. Semen specimen must be supplied to laboratory on Monday morning.

All requirements will be given to the patient from Texas Fertility Center directly.

HUHNER (POST-COITAL): Available Monday through Friday 8:30 a.m.-4:00 p.m. Weekends and holidays by appointment only.

All arrangements and instructions will be given by Texas Fertility Center.

SEX PRESELECTION: Available Monday through Friday 8:30 a.m.-4:00 p.m. and weekends and holidays by appointment only.

Special instructions and explanations will be given to patients by Texas Fertility Center.

ANTISPERM ANTIBODIES TESTING WITH IMMUNOBEADS: Available Wednesday and Thursday mornings by appointment.

1) A fresh sperm specimen should be collected according to semen analysis protocol.

2) Blood will be collected according to endocrine testing protocol for wife.

ALPHAFETOPROTEINS: Available on Fridays.

Blood collection will be arranged with the physician on an individual basis.

ENDOCRINE STUDIES: See schedule for availability of each test.

1) Blood should be drawn in red top tube without serum separator or with syringe.

2) Call Texas Fertility Center for courier pick up.

3) Blood collected after 4:00 p.m. should be processed as follows:
   a) Let blood clot for 45 minutes.
   b) Spin down for 30 minutes at maximum speed.
   c) Remove serum with serological pipet without disturbing red cells and dispense into sterile tube.
   d) Place serum in freezer
   e) Call for courier pick up the following morning.

4) hCG: Urine qualitative should be collected in a sterile container. It should be the first morning urine.

CHROMOSOME STUDIES: Available Monday through Friday, 8:30 a.m.-4:00 p.m.

Blood:
1) Green top tube with **SODIUM HEPARIN ONLY**.
2) 2-3 cc. blood collected in sterile condition.
3) Mix blood by gentle inverting several times to prevent clotting.
4) Call for courier pick up.
5) Storage - can be stored up to 24 hours at room temperature in dark.

AMNIOTIC FLUID:
1) Draw 5 15 ml. centrifuge tubes (Corning-orange top)
2) 20-30 cc amniotic fluid.
3) Tube 1: 1 cc first amniotic fluid
   Tube 2,3 and 4: approximately 8 cc.amniotic fluid in each tube.
4) Tube 5: 1-2 cc. of amniotic fluid for AFP testing
5) Call for courier pick up ASAP.
6) Storage - Can be stored at room temperature and protected from light. **DO NOT REFRIGERATE OR FREEZE.**

SOLID TISSUES:
1) Tissue from aborted fetus, skin biopsy or ovarian biopsy must be collected in sterile container and sterile saline (0.85% NACL).
2) Call for courier pick up or preserve tissue overnight in refrigerator. **DO NOT USE FORMALINE OR ANY FIXATIVE** (i.e. Alcohol).

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Fourth Floor, MEDICAL PLAZA HOSPITAL
1612 West Humbolt
Fort Worth, Texas 76104
817-336-GIFT

Laboratory Requisitions

Patient name ______________________________ sex F ☐ M ☐

Requesting physician ______________________________

Bill to: ☐ doctor ☐ patient

Specimen type

whole blood ____________________

Semen ____________ ________

Serum ____________________

Amniotic fluid ____________________

Chorionic villi ____________________

Other ____________________

Date collected ____________________

Time collected ____________________

Andrology

- ☐ Semen analysis
- ☐ Semen analysis (post vasectomy)
- ☐ IUI sperm preparation
- ☐ IUI sperm preparation with capacitation
- ☐ Sperm preparation for cervical insemination
- ☐ HEPA (Hamster Eggs Penetration Assay)
- ☐ Post coital tast
- ☐ Sex preselection F M
- ☐ Antisperm Antibodies test
- ☐ Husband sperm cryopreservation

Genetics

Chromosome studies
- ☐ amniotic fluid
- ☐ blood
- ☐ chorionic villi
- ☐ fibroblasts

Hormones

- ☐ LH
- ☐ FSH
- ☐ Prolactin
- ☐ Progesterone
- ☐ HCG
- ☐ Testosterone
- ☐ DHEA
- ☐ E_2
- ☐ TSH
- ☐ T_3
- ☐ T_4
- ☐ Others

____

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____

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INFERTILITY INVESTIGATION

There are many methods used in evaluating the couple who experience infertility. In an attempt to standardize the infertility investigation, Texas Fertility Center presents the following basic plan. This plan is not meant to replace the physician's own methods but demonstrates how the Center can compliment the fertility workup.

Couples who enter the IVF/GIFT program, are required to have an RPR, hepatitis screen, HTLV III and Rubella screen (woman only). The Center also requires this panel for couples undergoing basic infertility workups. Many physicians in the ACOG advocate these blood tests for new obstetrical patients, thus adding further impetus to their acquisition.

A semen analysis should be collected to evaluate any male factor. Any abnormalities should be corrected. Texas Fertility Center has a strong committment, as noted in this manual, to provide complete lab assesssment and treatment of male infertility.

The following plan is concise and orderly in its approach to infertility. Should any test be found to be abnormal, correction is instituted and the evaluation continues.

I. CYCLE ONE

a. Establish ovulation using BBT charts, LH surge kit and ultrasound. Ultrasound may be done two days prior to anticipated. A follicle size of 18-20 mm. indicates ovulation is near. The LH surge kit (Ovuquick) augments timing. A sonogram should be performed post ovulation to confirm follicular collapse (ruling out LUF).

b. Post coital test may be performed since ovulation has been documented.

c. Post ovulation - Obtain a serum progesterone approximately seven days post ovulation (also at this time, serum prolactin, TSH, T4 if clinically indicated). Many labs obtain prolactin around 10:00 a.m. because of diurnal variations.

In summary, during the first cycle, the physician has accomplished:

1) confirmation of ovulation
2) post coital test
3) mid luteal serum progesterone (prolactin, TSH, T4)

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CYCLE II

Double barrier contraception is suggested this cycle.

a. HSG (hysteroscope optional) is performed about 3 days after menstrual flow stops.

b. Endometrial biopsy is done approximately two days prior to onset of menses. A BBT chart or LH surge kit may be used for biopsy timing.

During Cycle II, the physician has determined uterine integrity, tubal patency and adequacy of the endometrial lining.

If no abnormalities are found, the physician may elect to have the patient undergo several cycles of timed intercourse.

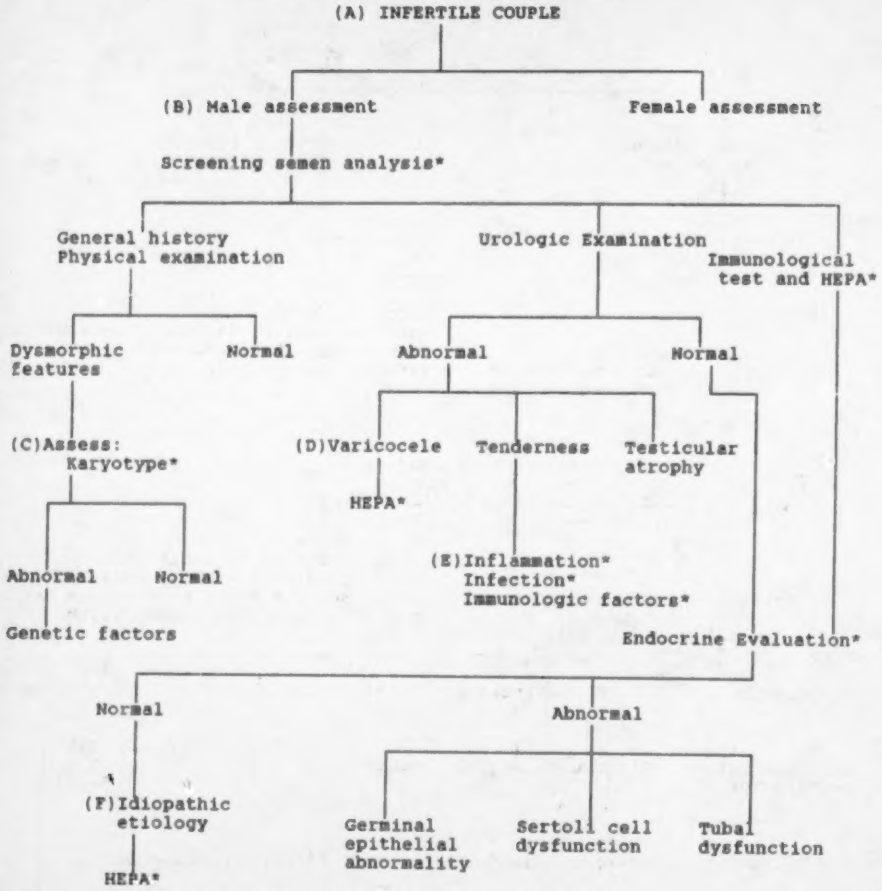
III. LAPAROSCOPY

A final diagnostic procedure in which the physician may perform "Incidental GIFT".

The Texas Fertility Center can assist the physician with:

- -Male Factor evaluation
- -documentation of ovulation
- -providing facilities for the PCT
- -obtaining RPR, hepatitis screen, HTLV III and Rubella
- -performing required endocrine testing, midluteal serum progesterone, prolactin, TSH, T4.
- -assistance in arranging the HSG and EMB
- -assistance in the "Incidental GIFT"
- -complete ancillary services to correct abnormal tests

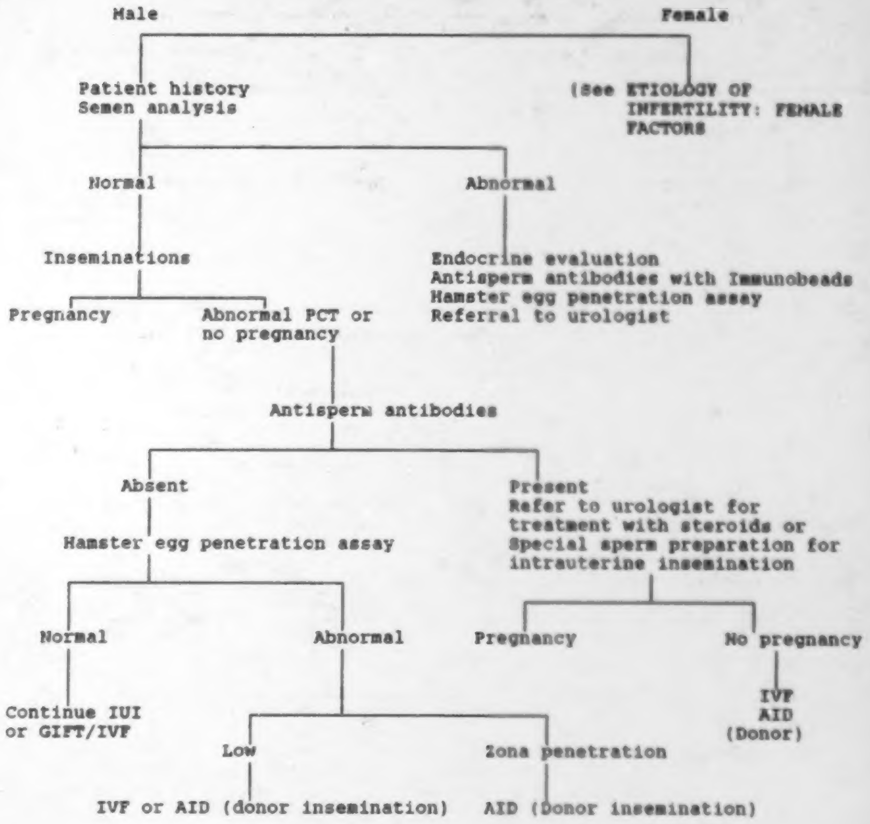
ETIOLOGY OF INFERTILITY: MALE FACTORS


(A) INFERTILE COUPLE
(B) Male assessment
Female assessment
Screening semen analysis*
General history
Physical examination
Urologic Examination
Immunological test and HEPA*
Dysmorphic features
Normal
Abnormal
Normal
(C)Assess: Karyotype*
(D)Varicocele
Tenderness
Testicular atrophy
HEPA*
Abnormal
Normal
(E)Inflammation*
Infection*
Immunologic factors*
Genetic factors
Endocrine Evaluation*
Normal
Abnormal
(F)Idiopathic etiology
HEPA*
Germinal epithelial abnormality
Sertoli cell dysfunction
Tubal dysfunction

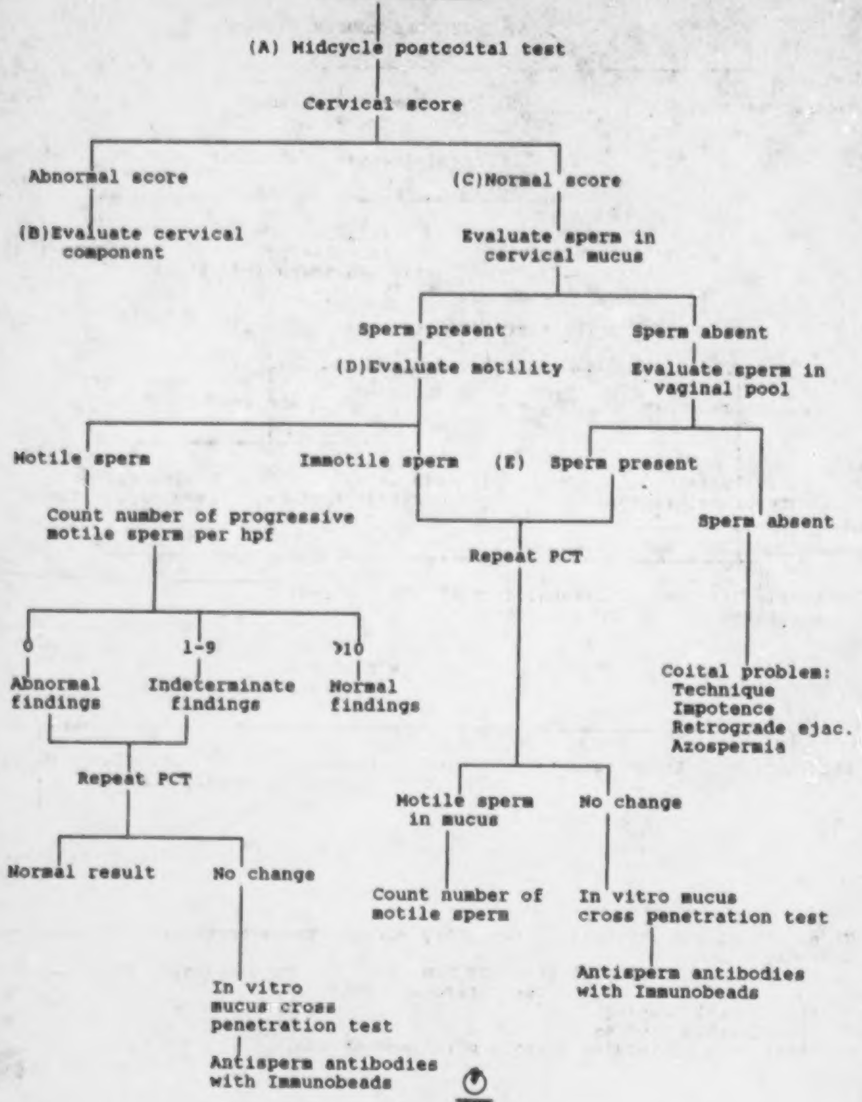
Texas Fertility Laboratories offers:
- *Semen Analysis
- *Endocrine and Chromosonal Studies
- *Antisperm Antibodies Testing with Immunobeads
- *Hamster Egg Penetration Assay (HEPA)
- *Donor Insemination
- *Sperm Washing

INFERTILITY WORKUP

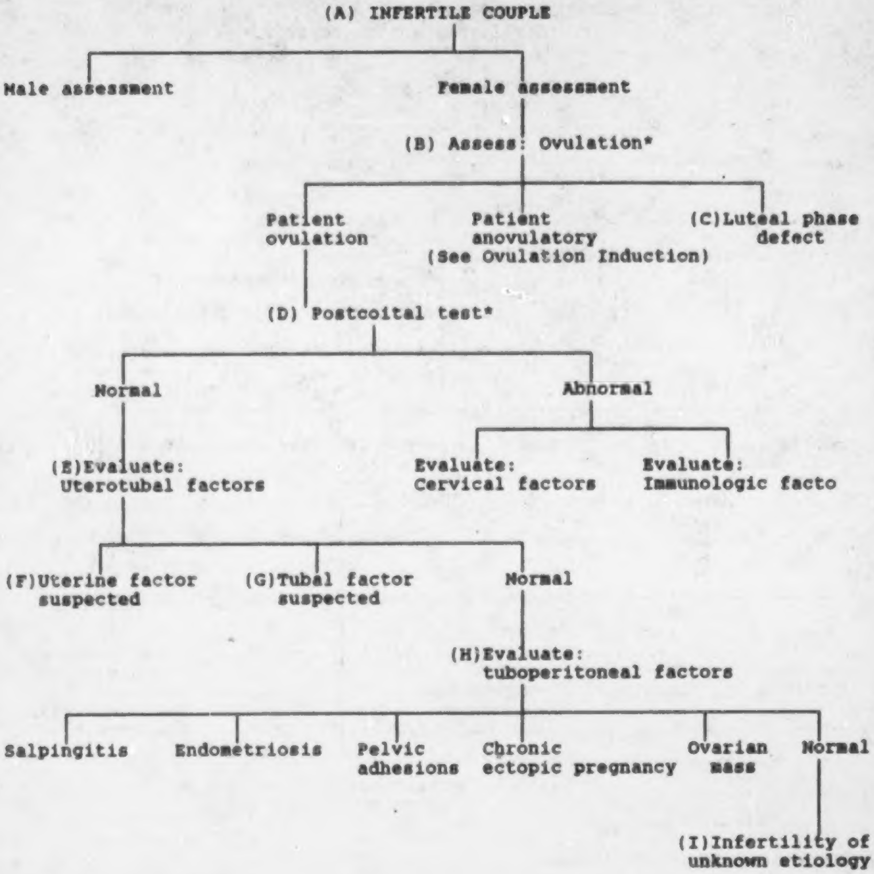
(If presents at Texas Fertility Center)


Male
Female
Patient history
Semen analysis
(See ETIOLOGY OF INFERTILITY: FEMALE FACTORS
Normal
Abnormal
Inseminations
Endocrine evaluation
Antisperm antibodies with Immunobeads
Hamster egg penetration assay
Referral to urologist
Pregnancy
Abnormal PCT or no pregnancy
Antisperm antibodies
Absent
Present
Refer to urologist for treatment with steroids or Special sperm preparation for intrauterine insemination
Hamster egg penetration assay
Normal
Abnormal
Pregnancy
No pregnancy
Continue IUI or GIFT/IVF
IVF
AID
(Donor)
Low
Zona penetration
IVF or AID (donor insemination)
AID (Donor insemination)

ADMINISTRATION OF POSTCOITAL TEST: SPERM COMPONENT


(A) Midcycle postcoital test
Cervical score
Abnormal score
(B)Evaluate cervical component
(C)Normal score
Evaluate sperm in cervical mucus
Sperm present
(D)Evaluate motility
Sperm absent
Evaluate sperm in vaginal pool
Motile sperm
Immotile sperm
(E)
Sperm present
Sperm absent
Count number of progressive motile sperm per hpf
Repeat PCT
0
1-9
>10
Abnormal findings
Indeterminate findings
Normal findings
Coital problem:
Technique
Impotence
Retrograde ejac.
Azospermia
Repeat PCT
Motile sperm in mucus
No change
Normal result
No change
Count number of motile sperm
In vitro mucus cross penetration test
Antisperm antibodies with Immunobeads
In vitro mucus cross penetration test
Antisperm antibodies with Immunobeads

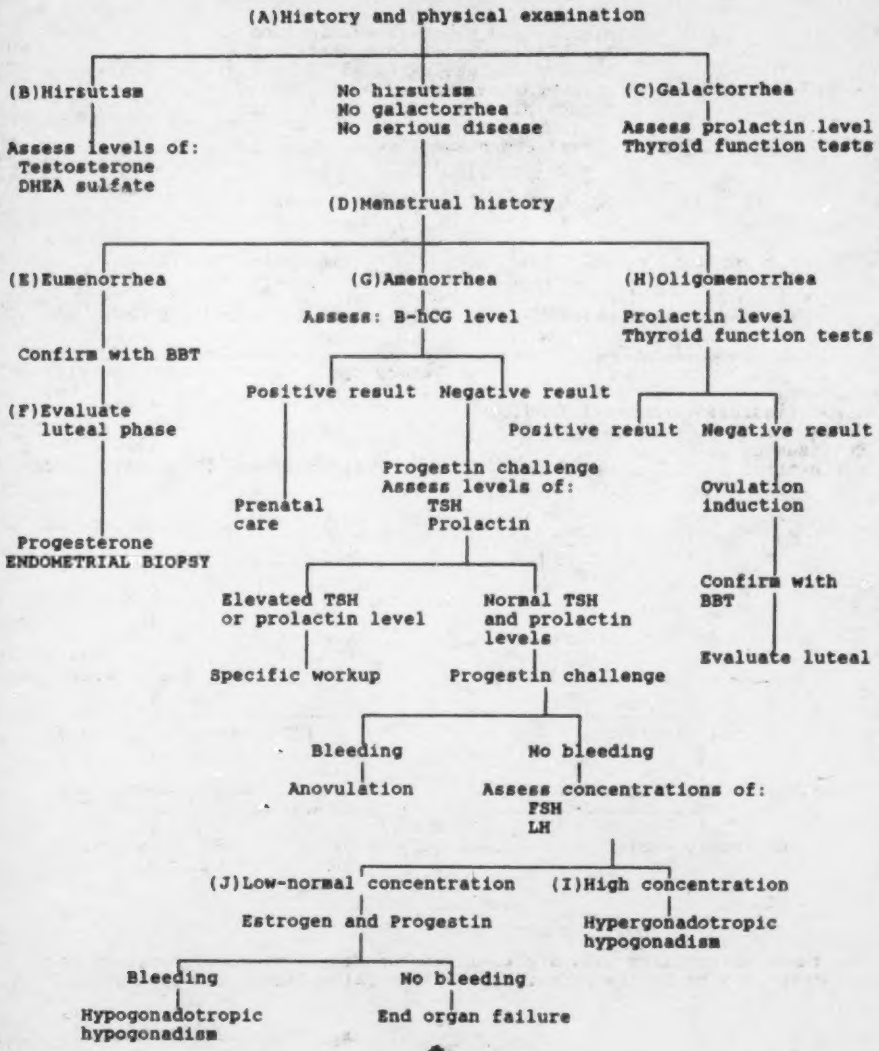
ETIOLOGY OF INFERTILITY: FEMALE FACTORS


(A) INFERTILE COUPLE
Male assessment
Female assessment
(B) Assess: Ovulation*
Patient ovulation
Patient anovulatory (See Ovulation Induction)
(C)Luteal phase defect
(D) Postcoital test*
Normal
Abnormal
(E)Evaluate: Uterotubal factors
Evaluate: Cervical factors
Evaluate: Immunologic facto
(F)Uterine factor suspected
(G)Tubal factor suspected
Normal
(H)Evaluate: tuboperitoneal factors
Salpingitis
Endometriosis
Pelvic adhesions
Chronic ectopic pregnancy
Ovarian mass
Normal
(I)Infertility of unknown etiology

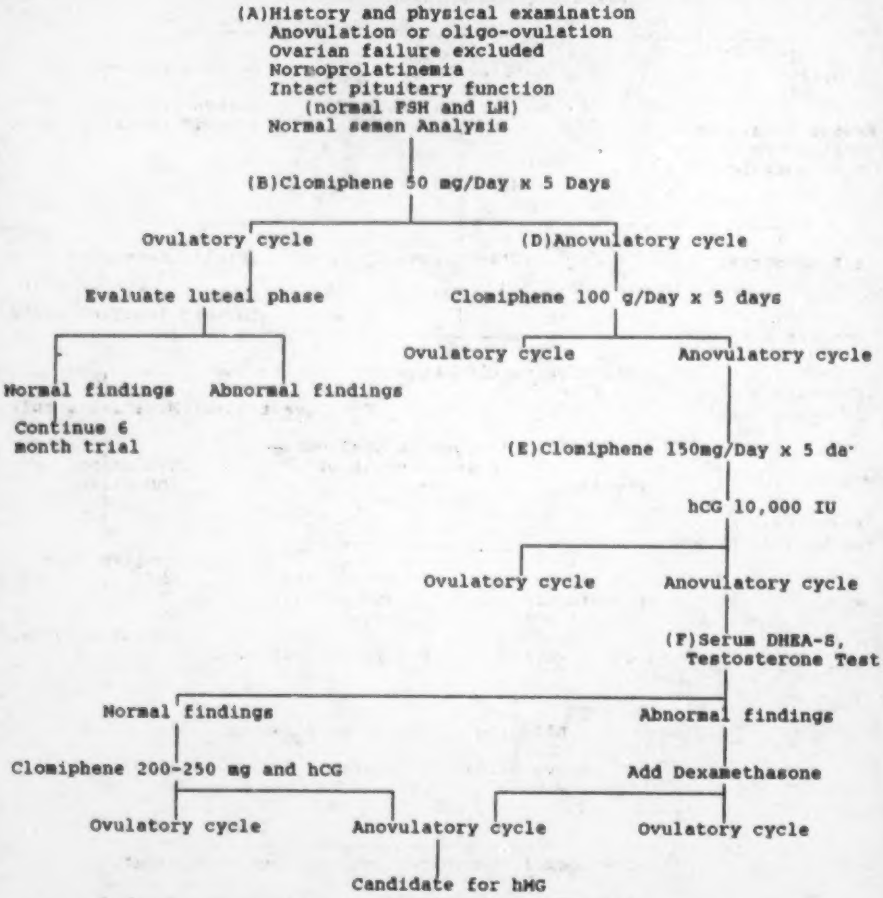
To assist in the physician's fertility workup, Texas Fertility Laboratories provides:

- *Endodrine Lab Studies (E2, FSH, LH, TSH, T4, Progesterone, Prolactin, Testosterone, DHEAS)
- *Postcoital Testing
- *Sonographic Studies
- *Antisperm Antibodies Testing with Immunobeads

Evaluation of OVULATORY FUNCTION

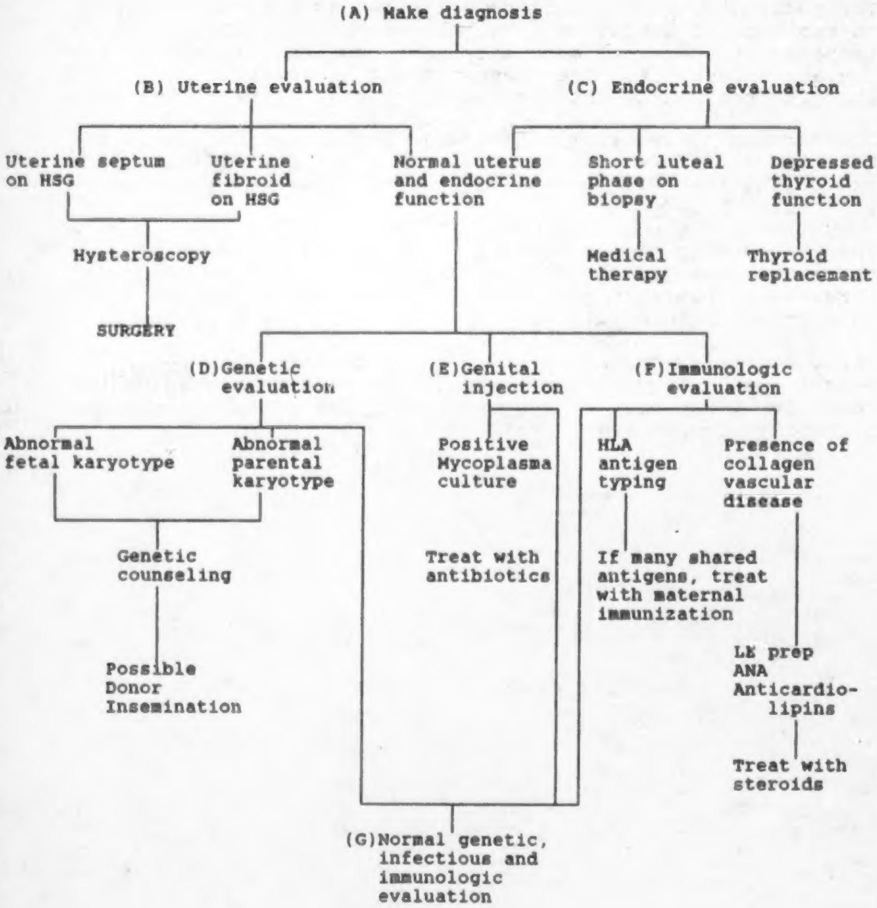

(A)History and physical examination
(B)Hirsutism
Assess levels of: Testosterone DHEA sulfate
No hirsutism No galactorrhea No serious disease
(C)Galactorrhea
Assess prolactin level Thyroid function tests
(D)Menstrual history
(E)Eumenorrhea
Confirm with BBT
(F)Evaluate luteal phase
Progesterone ENDOMETRIAL BIOPSY
(G)Amenorrhea
Assess: B-hCG level
Positive result
Negative result
Prenatal care
Progestin challenge Assess levels of: TSH Prolactin
Elevated TSH or prolactin level
Specific workup
Normal TSH and prolactin levels
Progestin challenge
Bleeding
Anovulation
No bleeding
Assess concentrations of: FSH LH
(J)Low-normal concentration
Estrogen and Progestin
Bleeding
Hypogonadotropic hypogonadism
No bleeding
End organ failure
(I)High concentration
Hypergonadotropic hypogonadism
(H)Oligomenorrhea
Prolactin level Thyroid function tests
Positive result
Negative result
Ovulation induction
Confirm with BBT
Evaluate luteal

Patient candidate for
OVULATION INDUCTION with CLOMIPHENE CITRATE


(A)History and physical examination
Anovulation or oligo-ovulation
Ovarian failure excluded
Normoprolatinemia
Intact pituitary function
(normal FSH and LH)
Normal semen Analysis
(B)Clomiphene 50 mg/Day x 5 Days
Ovulatory cycle
(D)Anovulatory cycle
Evaluate luteal phase
Clomiphene 100 g/Day x 5 days
Ovulatory cycle
Anovulatory cycle
Normal findings
Abnormal findings
Continue 6
month trial
(E)Clomiphene 150mg/Day x 5 da
hCG 10,000 IU
Ovulatory cycle
Anovulatory cycle
(F)Serum DHEA-S,
Testosterone Test
Normal findings
Abnormal findings
Clomiphene 200-250 mg and hCG
Add Dexamethasone
Ovulatory cycle
Anovulatory cycle
Ovulatory cycle
Candidate for hMG

For those infertility patients resistant to Clomid therapy, Pergonal (hMG) treatment may be initiated using Texas Fertility Center and laboratory.

Patient with HABITUAL ABORTION


(A) Make diagnosis
(B) Uterine evaluation
(C) Endocrine evaluation
Uterine septum on HSG
Uterine fibroid on HSG
Normal uterus and endocrine function
Short luteal phase on biopsy
Depressed thyroid function
Hysteroscopy
Medical therapy
Thyroid replacement
SURGERY
(D)Genetic evaluation
(E)Genital injection
(F)Immunologic evaluation
Abnormal fetal karyotype
Abnormal parental karyotype
Positive Mycoplasma culture
HLA antigen typing
Presence of collagen vascular disease
Genetic counseling
Treat with antibiotics
If many shared antigens, treat with maternal immunization
Possible Donor Insemination
LE prep
ANA
Anticardio-lipins
Treat with steroids
(G)Normal genetic, infectious and immunologic evaluation

POSTCOITAL TESTING

The postcoital test should be performed as near as possible to the time of ovulation. You may use basal body temperature, cervical mucous changes, hormonal assays or an ovulation test kit. The couple should be instructed to abstain from sexual intercourse for 2 days prior to the test.

The morning of the test, the couple should be instructed to have sexual intercourse and then report to the office for the postcoital test within 2-6 hours or as deemed by the physician.

The presence in the endocervix of an adequate number of motile spermatozoa suggests a favorable mucous and adequate survival of sperm in the cervix; it excludes cervical factors as a cause of infertility.

Texas Fertility Center is equipped to perform this test 7 days a week. If you plan to have this test completed on the weekend, please make arrangements with Texas Fertility Center by Friday of that week.

ULTRASOUND

Fertility studies involve the use of ultrasound which provides an excellent image of the pelvis. Texas Fertility Laboratories and Texas Fertility Center provide this imaging capability with the Ultramark 4 A ultrasound machine. The sonogram machine includes linear, sector and transvaginal scanning. Using the transvaginal scan, follicular growth can be documented which can predict ovulation.

By documenting ovulation, the physician may perform various fertility tests or inseminations. Physicians are encouraged to use the Ultramark 4A in assessing their fertility patients either by performing the sonograms themselves or having Texas Fertility Center personnel perform the sonogram. The Center will then notify the physician of the ultrasound exam results.

ADDENDUM: Transvaginal sonography exams are also useful in early pregnancy especially for evaluating threatened miscarriage, dating or pregnancy confirmation. The sonogram is available at Texas Fertility Center for such studies.

DONOR SPERM FOR ARTIFICIAL INSEMINATION

Donor sperm from an AATB (American Association of Tissue Banking) accredited sperm bank is available through Texas Fertility Center. Extensive testing and investigation of the donor is accomplished over a 6 month period before the sperm is available for use in artificial insemination.

A comprehensive family history is taken regarding ethnic background and possible genetic diseases including any history of heart disease, hypertension, diabetes or psychological disorders. Any diseases that run in the family are investigated. Donors are screened for Tay Sach's disease, B Thalassemia and sickle cell anemia. The sperm bank offers chromosome blood studies to exclude the possibility of chromosome rearrangement if required by the patient.

A sperm specimen is accepted for freezing on the basis of count, motility and morphology.

The donor's blood is typed and all donors are tested over a 6 month period for AIDS, CMV, Hepatitis, Herpes, syphilis, Chlamydia, gonorrhea, mycoplasma and ureaplasma. A GC (gonorrhea) culture is taken once a month.

The frozen specimen is released for use only if the donor presents no genetically transmitted diseases and no recurring diseases or disorders in his family history **AND** if he is free of communicable diseases after the 6 month testing period.

The sperm bank assures a count in excess of 20 million of sperm per sample.

The patient chooses the donor from a Donor Profile supplied by Texas Fertility Center. It provides the patient with information regarding the donor's origin, blood type, eye color, hair color and type, complexion, height, body build, years of education and occupation. The patient is asked to pick 3 donors by order of preference. To insure delivery at the optimal time for insemination, Texas Fertility Center prefers to order the specimen 1 week prior to anticipated use. Texas Fertility Center prepares the specimen for intrauterine or cervical insemination dependent upon the physician's request.

To obtain donor semen, have your office call the nurse coordinator (336-GIFT). You may use Texas Fertility Center's facilities for insemination. If you are not available at the time of insemination, arrangements can be made for the patient to be treated at TFC by staff.

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HITS
(Hysteroscopic Intratubal Transfer of Sperm)

The male and female share equally in the responsibility of infertility. Forty percent (40%) of the time, there is a male problem, forty percent (40%) of the time there is female problem, and twenty percent (20%) of the time there is a shared problem. Recent data seem to support the position that male problems may actually dominate the field of infertility.

Enabling the egg and sperm to come together in a healthy fallopian tube should help solve many of today's fertility problems.

Through the Texas Fertility Center, patients will be evaluated for infertility by their local gynecologist using the standard Serono infertility evaluation forms. Once a patient is judged to be ovulatory (spontaneous or induced), she may become a candidate for hysteroscopic intratubal transfer of sperm (HITS).

Candidates are presumed to have at least one normal fallopian tube and either a cervical mucus factor and/or a possible male factor for infertility. Careful documentation of Huhner tests and seminal parameters should also be available and accurately recorded prior to the HITS procedure. If a patient is ovulating on the side which the patient has a normal fallopian tube, four HITS cycles should be carried out before moving on to GIFT or IVF.

HITS will be performed in lieu of intrauterine insemination when a patient is judged to be an appropriate candidate.

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"INCIDENTAL GIFT PROCEDURE"

The final diagnostic procedure in a routine infertility work up generally is a laparoscopy. If the patient's fallopian tubes are patent (proven by hysterosalpingogram), strong consideration should be given to placing her eggs along with the husband's sperm into the patient's tube(s) in conjunction with the laparoscopy.

This "incidental GIFT" can be performed on all infertility patients with patent tubes at little extra expense and may result in pregnancy. The Texas Fertility Center employs a programmed stimulation protocol which allows the scheduling of a diagnostic laparoscopy and "incidental GIFT" 2 months in advance. The stimulation cycle requires a minimum of laboratory tests which decreases the overall cost to the patient. One must realize that fewer eggs may be retrieved as opposed to the standard protocols. Yet the "incidental GIFT" offers a realistic chance for pregnancy and as reported by Dr. Asch, the physician bypasses any defect in gamete transport.

When considering "incidental GIFT", Texas Fertility Center can assist the physician with the programmed cycle. In general, the patient will need: 2 ultrasound studies, one E2 and LH value and the use of one LH surge kit. The physician can perform the laparoscopy and administer any needed treatment (lysis of adhesions, laser, etc.) The follicles are aspirated prior to treatment and the GIFT is performed afterwards. The physician may elect to participate directly in the "incidental GIFT" or use the Texas Fertility Center on-call physician.

ESTIMATED COST:	$170.00	Ultrasound series
	55.00	E2 serum
	45.00	LH serum
	70.00	LH surge kit
	400.00	Pergonal (10 amps)
	400.00	Laboratory-GIFT processing
	150.00	HCG injection
	500.00	Professional fee

The above protocol may also be used for "incidental IVF-ET" procedures with an additional laboratory and transfer fee.

For childless couples (over 33 years of age) or the patient undergoing a second look fertility laparoscopy, a regular GIFT stimulation protocol as opposed to "incidental GIFT" should be considered.

* If tubal surgery is being contemplated with less than a 20% chance of success anticipated, a follicle aspiration (incidental) at the time of surgery with subsequent IVF-ET is an option worth considering.

A PATIENT'S GUIDE TO THE INFERTILITY INVESTIGATION

1) Schedule semen analysis

CYCLE I

2) Contact your physician when you begin the first day of good menstrual flow. If this occurs on the weekend, call the following Monday.

3) Please schedule an ultrasound for Cycle Day 11 for follicle studies. Your physician will inform you as to the need for further studies.

4) The postcoital test will be scheduled using the BBT chart or the LH surge kit in conjunction with ultrasound. This is generally Cycle Day 14 and 48 hours abstinance is suggested prior to PCT.

5) An ultrasound may be performed after the postcoital test to document collapse of the follicle.

6) Seven days after ovulation, report for blood work.

CYCLE 2

If you do not begin menstrual flow 16 days post ovulation, report for a pregnancy test. If you begin your flow, see Item #2. Please use double barrier contraception this cycle (foam and condoms)

7) A hysterosalpingogram will be done approximately 3 days after vaginal bleeding stops.

8) An endometrial biopsy will be done approximately 2 days before you begin menstrual flow.

CONTACT PERSONNEL

Janina Michalowska, Ph. D. Laboratory Director	336-GIFT 292-5891 Home
Karen Walker, R.N. Nurse Coordinator	336-GIFT 346-0912 Home
Susan Schenck Business Manager	336-GIFT
David M. Wooldridge, M.Ed. Director of Marketing	336-GIFT

TEXAS
FERTILITY
CENTER

4th Floor, HCA Medical Plaza Hospital, 1612 W. Humbolt, Fort Worth, TX 76104, 817-336-GIFT

Dear Doctor,

We have enclosed "Possible Alternatives to In-Vitro Fertilization and Embryo Transfer at Texas Fertility Center". Listed in this pamphlet are alternative procedures, many of which you, the physician, can perform in your office or take an active role in at Texas Fertility Center.

Every patient seen at Texas Fertility Center receives this pamphlet, and you are certainly encouraged to make it available to your own infertility couples.

Sincerely,

Texas Fertility Center

POSSIBLE ALTERNATIVES TO IN-VITRO FERTILIZATION AND EMBRYO TRANSFER AT TEXAS FERTILITY CENTER

TEXAS
FERTILITY
CENTER

ASSISTED REPRODUCTIVE TECHNOLOGY

Texas Fertility Center
4th Floor, HCA Medical Plaza Hospital
1612 W. Humbolt
Fort Worth, TX 76104
817-336-GIFT

Possible Alternatives to In-Vitro Fertilization and Embryo Transfer

Before a couple attempts IVF-ET, they should be certain that no other form of assisted reproductive technology exists which will be more appropriate to *their* particular situation.

Since the cause of the problem determines the solution, the couple's physician should identify the cause of their infertility in order to determine whether IVF-ET is the best solution.

The couple should seek a physician with expertise in infertility, who then will perform baseline tests on both the man and woman. Within a period of one to two months, one should be able to diagnose the problem and prescribe appropriate treatment. If the physician cannot ascertain the problem, IVF-ET can act as a means of both diagnosing and treating the couple's infertility. The physician, on the other hand, may recommend alternate methods of assisted reproductive technology before proceeding to IVF-ET. These methods of therapeutic gamete-zygote-related technology will be explained below.

Therapeutic Gamete-Zygote-Related Technologies

Therapeutic Gamete-Zygote-Related technology requires at least one functional fallopian tube and includes one or more of the following procedures: recruitment, insemination, egg or zygote transfer, and/or sperm transfer into the woman's reproductive tract. A zygote is defined as a fertilized egg (embryo). Whereas "gamete-related technology" relies on in vivo fertilization (fertilization in the body), "zygote-related technology" relies on in vitro fertilization (fertilization of the female gamete(egg) by the male gamete(sperm) in the laboratory) with subsequent transfer to the fallopian tube(s). The ultimate goal is a successful pregnancy.

IVF-ET refers to in vitro fertilization with subsequent transfer of the embryo(s) to the uterus, thus bypassing the fallopian tube(s). Fertilization occurs inside laboratory incubators which require strict monitoring by the gamete physiologist and embryologist. The following conditions are treatable by IVF-ET: female organic pelvic disease, severe male factor, sperm antibodies, and unexplained infertility.

In contrast, therapeutic gamete-zygote-related technology (listed below) is indicated only for infertility treatment not pertaining to female organic pelvic disease. A couple should initially consider the least invasive and/or least sophisticated procedure to achieve pregnancy.

1. Intrauterine Insemination

Intrauterine Insemination (IUI) refers to the injection of specially prepared sperm into the uterine cavity. A catheter is passed through the cervical canal and into the uterine cavity where the sperm is deposited near the opening of the fallopian tubes. IUI is suited for the treatment of male infertility, sperm antibodies, cervical factor, and/or unexplained infertility. Semen collected from the male is initially processed by separating the sperm from the milky seminal fluid. The sperm is then washed several times and incubated in special medium prepared by the Texas Fertility Center's andrology laboratory. This medium acts to enhance the sperm's fertilization capacity. The capacitated highly motile sperm is ready for injection into the uterus of a woman who has received fertility drugs. The fertility drugs act to encourage the release of a number of eggs at the time of ovulation (superovulation), thus increasing the chances for fertilization by the sperm.

2. Artificial Insemination by Donor

Artificial insemination by donor involves the use of frozen donor sperm which is obtained from a licensed sperm bank. The bank, which meets criterion set by the American Fertility Society, meticulously screens for underlying venereal diseases including acquired immune deficiency syndrome (AIDS). The sperm is deposited into the vagina about the cervix at the time of ovulation and will result in pregnancy in a majority of women provided several attempts are made and no underlying reproductive disease exists. In certain cases, IUI and/or superovulation may be required.

3. Hysteroscopic Intratubal Transfer of Sperm(HITS)

A hysteroscope uses fiberoptics to visualize the uterine cavity and one can then view the opening of the fallopian tubes. Using transvaginal ultrasound, available at Texas Fertility Center, one may document which ovary will release an egg at the time of ovulation. Just prior to ovulation, the miniature hysteroscope is passed through the cervix into the uterine cavity and the physician can visualize the opening of the fallopian tube whose ovary is destined to ovulate. Under direct visualization, a catheter is passed into the fallopian tube where specially prepared sperm is injected. Superovulation can also be employed to facilitate fertilization. The chances for fertilization are greatly enhanced by depositing sperm directly into the fallopian tube of the ovulating ovary.

This procedure is for women who have failed IUI, severe male factor infertility, tubal reanastonosis, as well as other refractory infertility problems. A local anesthetic is all that is required to perform HITS.

4. Gamete Intrafallopian Tubal Transfer

GIFT involves the injection of one or more eggs mixed with washed, enhanced, and incubated sperm directly into the fallopian tube(s). GIFT is usually performed at the time of laparoscopy on a woman who has been given fertility drugs to increase the number of eggs retrieved. Under direct visualization via the laparoscope, the mixture of eggs and sperm is injected into the fallopian tube(s) where the egg is fertilized by sperm to form an embryo. The embryo(s), or fertilized egg, is then transported to the uterus where implantation and subsequent pregnancy occurs. Since fertilization normally occurs in the fallopian tube(s), GIFT's advantage over IUI is the placement of both egg(s) and sperm in the tube simultaneously. GIFT eliminates any concern over the ability of the ends of the fallopian tube(s) to pick up the egg at ovulation time. In GIFT, fertilization occurs in the human body and the embryo(s) is not exposed to outside hostile elements as in IVF. Any capacitation of the egg(s), sperm, and/or embryo(s) by the tube is possible using GIFT.

There are disadvantages with this procedure in that fertilization cannot be documented unless pregnancy occurs. This becomes extremely important in cases of severe male infertility where the husband's sperm may fail to fertilize his partner's eggs. IVF provides direct evidence of fertilization and doctors may recommend that GIFT be performed concurrently with in vitro fertilization to document fertilization of eggs. The American Fertility Society states that GIFT should be performed only in facilities that have IVF capabilities, such as Texas Fertility Center.

Success rates for GIFT tend to be higher than IVF/ET. This may be due to it being a simpler procedure to perform than IVF and not requiring a sophisticated laboratory for fertilization.

GIFT can be performed, in our opinion, only if there is no evidence of tubal disease. Even though the tube is open, tubal disease can be present.

Our team performs GIFT on infertility cases which involve male infertility, cervical factor, endometriosis, and unexplained infertility. We preclude those cases where there is a history of, or clinical evidence of, female pelvic disease, since there is a high incidence of tubular or ectopic pregnancy.

5. GIFT Performed in Combination with IVF/ET

A woman, who is to have IVF/ET, may have fallopian tubes which appear normal and no history of tubal disease. In this case, if enough eggs are retrieved at the time of laparoscopy, our team will sometimes perform a GIFT with several leftover eggs. Thereupon, 48 hours later, the embryos derived from the IVF are transferred back into the woman's uterus. By using the combination of GIFT and IVF/ET a higher pregnancy rate can be achieved. As mentioned before, a major advantage in performing IVF in combination with GIFT is that direct confirmation of fertilization of the woman's egg(s) by her partner's sperm is possible.

In order to combine GIFT and IVF, laparoscopy is required and the couple may experience a higher incidence of multiple pregnancies.

6. Zygote Intrafallopian Transfer

Zygote Intrafallopian Transfer (ZIFT) initially involves ultrasound guided retrieval of a woman's eggs under a local anesthetic. IVF is then performed after the eggs are retrieved, thus confirming the fertilization of the woman's eggs by her partner's sperm. After fertilization, and approximately 24 hours post retrieval, the fertilized eggs (zygotes) are transferred into the woman's fallopian tube(s) via the laparoscope. The method is similar to that of GIFT except that in ZIFT, a fertilized egg(s) is transferred into a fallopian tube under local anesthesia. The women must have at least one normal fallopian tube and no history of pelvic adhesive disease.

ZIFT is ideal for male factor infertility. Whereas fertilization cannot always be confirmed in GIFT, zygote intrafallopian transfer establishes fertilization in the laboratory, and makes use of the normal fallopian tubal function to augment embryo implantation and pregnancy. ZIFT also proves useful in the treatment of antisperm antibodies or if embryo transfer into the uterus is deemed too difficult.

Both ultrasound guided egg retrieval and laparoscopic zygote transfer are routinely done under local anesthetic which greatly diminishes operative risk to the patient.

Should excess embryos be present after ZIFT, one may use cryopreservation or transfer the embryos directly to the uterine cavity (as in standard IVF/ET).

Our team anticipates a higher pregnancy rate with ZIFT because of: 1) documented fertilization of the eggs in our laboratory, 2) the transfer of the zygotes within approximately 24 hours of retrieval, thus decreasing exposure time to outside elements, and 3) the use of the fallopian tube to augment embryo implantation and pregnancy.

7. Embryo Freezing(Cryopreservation)

Employing superovulation protocols to enhance egg recruitment, one frequently finds excess embryos exist after performing IVF, GIFT, or ZIFT. Recent developments in cryopreservation of excess embryos permit their storage for months or years. These embryos, upon thawing, may be replaced by embryo transfer into the woman's uterine cavity immediately after ovulation in a normal menstrual cycle. One to three embryos are usually transferred. In this manner, enough eggs can be harvested so that several months of transfer with resultant pregnancy may be attempted. The use of normal cycles for transfer is thought to be advantageous because physiologic hormone levels provide a more receptive environment for the fertilized egg. Our team at the Texas Fertility Center feels that cryopreservation will increase the overall pregnancy rate associated with IVF/ET. In the *future*, some physicians believe that all embryos will undergo cryopreservation and be replaced in normal cycles.

During the freezing and thawing phases, certain embryos do not survive. This may be a selection process which removes those embryos of poor quality. Also there has been shown to be *no* increase in birth defects using cryopreservation. Some couples may wish not to participate in embryo cryopreservation because of moral, ethical, or religious concerns, and our team at the Texas Fertility Center will honor their decision.

As seen in the local news media, there is a constant evolution of new reproductive technology which we, at the Texas Fertility Center, must evaluate. In the near future, one may find the need for 1) sperm micro manipulation--the actual injection of sperm into the egg under a microscope, providing artificial insemination for severe male factor, 2) cryopreservation of eggs as opposed to embryos, and finally, 3) the quest for that magic glue which binds the embryo to the uterus with resulting pregnancy.

The availability of all the new and fascinating technologies place awesome responsibility on the medical profession, which we, as physicians, take seriously. In the final analysis, we at the Texas Fertility Center believe that our responsibility is: 1) to provide infertile couples realistic expectations, 2) to keep them as informed as possible in order that rational judgments dealing with their problems can be made, and 3) to provide the highest level of expertise in a caring environment.

IVF/GIFT SURVEY

CLINIC NAME: IVF Program - University of Texas Medical Branch
ADDRESS: Department of Obstetrics and Gynecology
University of Texas Medical Branch
Galveston, Texas 77550

CONTACT PERSON: Manubai Nagamani, M.D.
PHONE NUMBER: (409) 761-3985

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/1/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private _______
   - (b) Community hospital based _______
   - (c) University based XX
   - (d) Other (explain) _______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   - (a) Physicians 1
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses -
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians -
   - (g) Psychologists/Counselors -
   - (h) Secretaries 1
   - (i) Other (specify) _______

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1984 GIFT 1987

9. How many different patients were stimulated?
1987 IVF 15 1988 IVF -
GIFT 3 GIFT 12

10. How many stimulation cycles were performed?
1987 IVF 15 1988 IVF -
GIFT 3 GIFT 12

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 15 1988 -

How many embryo transfer cycles were performed?
1987 15 1988 -

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 3 1988 12

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0% 1988 0 0%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 15 100% 1988 IVF - -%
GIFT - -% GIFT - -%
(b) Endometriosis:
1987 IVF - -% 1988 IVF - -%
GIFT - -% GIFT - -%
(c) Male infertility:
1987 IVF - -% 1988 IVF - -%
GIFT - -% GIFT 1 8%
(d) Unexplained infertility:
1987 IVF - -% 1988 IVF - -%
GIFT - -% GIFT 11 91%
(e) Other (explain): ____________
1987 IVF - -% 1988 IVF - -%
GIFT - -% GIFT - -%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 3 20% 1988 IVF - -%
GIFT - -% GIFT 4 33%
(b) 31-35:
1987 IVF 2 13% 1988 IVF - -%
GIFT 3 100% GIFT - -%
(c) 36-40:
1987 IVF 10 67% 1988 IVF - -%
GIFT - -% GIFT 7 59%

(d) 41-45:
1987 IVF - -% 1988 IVF - -%
GIFT - -% GIFT 1 8 %

(e) >45:
1987 IVF - -% 1988 IVF - -%
GIFT - -% GIFT - -%

16. How many clinical pregnancies were produced?
1987 IVF 3 1988 IVF -
GIFT 1 GIFT 3

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 3 1988 IVF -
GIFT 1 GIFT 2

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF - 1988 IVF -
GIFT - GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF -
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 3 20 % Twins - 1
GIFT 1 33 %

1988 IVF - -%
GIFT 3 25 %

21. What are the qualifications of the director of the embryo laboratory? Ph.D.

22. Who supervises the laboratory director? IVF Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
CAP (For estradiol assays)

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No, have not applied.

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ______
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ______
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: BAYLOR GIFT/IVF PROGRAM
ADDRESS: BAYLOR COLLEGE OF MEDICINE
1 BAYLOR PLAZA
HOUSTON, TEXAS 77030

CONTACT PERSON: Dr. William E. Gibbons [illegible] 713 799-8474
PHONE NUMBER: (713)798-7500 X277

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12-88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based ______
   (c) University based X
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 4

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 10

6. How many other professionals participate in your clinic?
   (a) Physicians ______
   (b) Laboratory Scientists (PhDs) 2
   (c) Nurses 3
   (d) Embryo Lab Technicians/Technologists 4
   (e) Other Lab Technicians/Technologists ______
   (f) Radiology (Ultrasound) Technicians 3
   (g) Psychologists/Counselors 1
   (h) Secretaries 2
   (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 6/83 GIFT 1/86

9. How many different patients were stimulated?
1987 IVF ~~196~~ [illegible] 195 1988 IVF 153
GIFT [illegible] No GIFT ______

10. How many stimulation cycles were performed?
1987 IVF 249 1988 IVF 261
GIFT ______ GIFT ______

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 159 [illegible] 1988 174

How many embryo transfer cycles were performed?
1987 134 1988 147

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 23 1988 18

13. What were the number and percentage of patients on IRB approved research protocols?
1987 249 100% 1988 261 100 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 68 34.3% 1988 IVF 39 28.7%
NOT SEPARATED ~~GIFT ___ ___% GIFT ___ ___%~~
(b) Endometriosis:
1987 IVF 76 38.4% 1988 IVF 54 39.7 %
NOT SEPARATED ~~GIFT ___ ___% GIFT ___ ___%~~
(c) Male infertility:
1987 IVF 48 24.2% 1988 IVF 65 47.8%
NOT SEPARATED ~~GIFT ___ ___% GIFT ___ ___%~~
(d) Unexplained infertility:
1987 IVF 12 6.1% 1988 IVF 5 3.7 %
NOT SEPARATED ~~GIFT ___ ___% GIFT ___ ___%~~
(e) Other (explain): Anovulation, cervical, PCO, normal
1987 IVF 33 ___% 1988 IVF 27 ___%
NOT SEPARATED ~~GIFT ___ ___% GIFT ___ ___%~~

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 36 18.2% 1988 IVF 33 24.3%
NOT SEPARATED ~~GIFT ___ ___% GIFT ___ ___%~~
(b) 31-35:
1987 IVF [illegible] 43.9% 1988 IVF 63 46.3%
NOT SEPARATED ~~GIFT ___ ___% GIFT ___ ___%~~
(c) 36-40:
1987 IVF 66 33.3% 1988 IVF 33 24.3%
NOT SEPARATED ~~GIFT ___ ___% GIFT ___ ___%~~

(d) 41-45:
1987 IVF 9 9.6% 1988 IVF 7 5.1 %
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 13 1988 IVF 21
GIFT 6 GIFT 5
IVF/GIFT 15 IVF/GIFT 12

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 7 1988 IVF 3
GIFT 2 GIFT 1
IVF/GIFT 9 IVF/GIFT 4

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 12
GIFT ___ GIFT 3
IVF/GIFT 6

19. How many ectopic pregnancies resulted?
1987 IVF 2 1988 IVF ___
GIFT 1 GIFT ___
IFV/GIFT 1 IVF/GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 7.7% triplets
GIFT - - % ___
IVF/GIFT 4 26.7% 2 sets twins; 2 sets triplets
1988 IVF 3 28.6% 6 sets twins (all u/s)
GIFT ___ ___% ___
IVF/GIFT 3 25% 3 sets twins

21. What are the qualifications of the director of the embryo laboratory? PHD - Has published papers on IVF Media, Quality Control, etc.

22. Who supervises the laboratory director? William E. Gibbons, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? YES

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? YES

27. Does the clinic train individuals in IVF or GIFT? YES
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 10
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists 6
    (d) Nurses 3
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The Baylor IVF Progam is a tertiary referral center in the Southwest for patients excluded by other IVF/GIFT programs ie. male factor, age >40, etc. Our program has an interest in male factor infertility. Since 1986 our overall non-male factor clinical pregnancy rate is 24.5%. In 1988 only 16% of pregnancies were not on-going. We had the first cryopreservation pregnancy in the Southwest. Our current on-going pregancy rate for frozen embryo transfer is 15-20%.

IVF/GIFT SURVEY

CLINIC NAME: OB & GYN Associates
ADDRESS: 7550 Fannin
Houston, Texas 77054

CONTACT PERSON: George M. Grunert, M.D.
PHONE NUMBER: 713-797-9123

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? November 19, 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 19

6. How many other professionals participate in your clinic?
   - (a) Physicians 4
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 6
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 1
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 1
   - (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1985

9. How many different patients were stimulated?
1987 IVF 74 1988 IVF 147
GIFT 90 GIFT 87

10. How many stimulation cycles were performed?
1987 IVF 103 1988 IVF 190
GIFT 125 GIFT 104

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 82 1988 170

How many embryo transfer cycles were performed?
1987 70 1988 145

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 102 1988 91

13. What were the number and percentage of patients on IRB approved research protocols?
1987 164 100% 1988 235 100% *See Addendum

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 40 54 % 1988 IVF 63 43 %
GIFT 24 27 % GIFT 18 23 %
(b) Endometriosis:
1987 IVF 6 8 % 1988 IVF 16 11 %
GIFT 36 40% GIFT 24 31 %
(c) Male infertility:
1987 IVF 16 22 % 1988 IVF 45 31 %
GIFT 3 8 % GIFT 10 13%
(d) Unexplained infertility:
1987 IVF 0 0% 1988 IVF 5 3 %
GIFT 8 9 % GIFT 7 9 %
(e) Other (explain): Cervical, DES exposure, Anovulation
1987 IVF 12 16% 1988 IVF 18 12%
GIFT 15 16% GIFT 19 24%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 37 50% 1988 IVF 49 33%
GIFT 67 75% GIFT 45 58%
(b) 31-35:
1987 IVF 18 24% 1988 IVF 39 27%
GIFT 3 3 % GIFT 2 3 %
(c) 36-40:
1987 IVF 10 14% 1988 IVF 34 23%
GIFT 12 13 % GIFT 22 28 %

(d) 41-45:
1987 IVF 9 12% 1988 IVF 25 17%
GIFT 8 9% GIFT 9 11%

(e) >45:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 0 0%

16. How many clinical pregnancies were produced?
1987 IVF 20 1988 IVF 40
GIFT 24 GIFT 16

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 14 1988 IVF 13
GIFT 22 GIFT 7

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 26 * See addendum
GIFT 0 GIFT 8 *See addendum

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 0
GIFT 3 GIFT 2

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 3 22% All twins
GIFT 3 14% All twins

1988 IVF 3 23% 2-Twins, 1-Triplets
GIFT 2 29% All Twinds

21. What are the qualifications of the director of the enbryo laboratory? Ph.D. in Gamete Physiology

22. Who supervises the laboratory director? George M. Grunert, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
Liaison with Baylor College of Medicine

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes (through Baylor College of Medicine)

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 4
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 2
    (d) Nurses 6
    (e) Other (explain) RIA Technician 2

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Our clinic deals with a large number of couples with male factor infertility. We are currently in the process of changing from a hospital based to a clinic based program with facilities for outpatient ultrasound guided recovery of oocytes for in vitro fertilization.

Addendum:

#13: All patient cycles were on IRB approved protocols.

#18: All patients for 1987 are delivered; 1988 patients are pregnant but not delivered

OGA
Obstetrical & Gynecological Associates

December 14, 1988

7550 FANNIN, HOUSTON, TEXAS 77054-1989, 713-797-9123
BRANCH OFFICE: 950 CORBINDALE, SUITE 205, HOUSTON, TEXAS 77024

The Honorable Ron Wyden
Chairman
Subcommittee on Regulation and Business Opportunities
Ste #1406
Longworth House Office Building
Washington, DC 20515

Dear Representative Wyden:

I have enclosed the IVF/GIFT data sheets from the Obstetrical and Gynecological Associates' program for the years 1987 and 1988. Please note that not all patients have completed their cycles for determination of pregnancy and fetal viability in 1988 and therefore the data has not been included.

Our pregnancy rate for GIFT appears to be lower than the norm. I feel this represents the fact that we have performed GIFT for a large number of patients with male factor and tubal factor infertility for whom IVF is not religiously or ethically accepted. Some of these patients would have been better served by IVF than GIFT.

Participating in this series are myself, Dr. Joseph Feste, Dr. Eberhard Lotze, and Dr. Rell Woodward of the OB & GYN Associates. Ovarian stimulation was performed by myself or by Drs. Luis Rodriguez, Emil Steinberger, or Russell Weideman of the Texas Institute for Reproductive Medicine and Endocrinology.

I certainly encourage your endeavor in obtaining accurate information for IVF and GIFT patients. The current climate of entrepreneurial medicine has certainly not always fostered truth in advertising.

If I can answer any questions or be of help to you in any other way, please do not hesitate to contact me.

Sincerely,

George M. Grunert, MD

George M. Grunert, M.D.

GMG:TLB

Enclosure: IVF/GIFT Survey

WARREN M. JACOBS, M.D.
STANLEY F. ROGERS, M.D.
JACK MOORE, M.D.
JOSEPH R. FESTE, M.D.
ROBERT R. FRANKLIN, M.D.
LEON J. DAILY, JR., M.D.
EBERHARD C. LOTZE, M.D.
LEROY J. LEEDS, M.D.
PETER K. THOMPSON, M.D.
THOMAS STRAMA, M.D.
JAMES R. GULLETT, M.D.
JOHN B. ROSS, M.D.
JOHN F. IRWIN, M.D.
RELL M. WOODWARD, M.D.
GEORGE M. GRUNERT, M.D.
MARK A. JACOBS, M.D.
MARY T. NEAL, M.D.
RACHEL A. THOMPSON, M.D.
VEASY C. BUTTRAM, JR., M.D.
BONNIE SNEAD STUMP, M.D.
GERI-LYNN FROMM, M.D.
WILLIAM J. SCHINDLER, M.D., PhD.
RODERICK F. McNEIL, ADMIN.

IVF/GIFT SURVEY

CLINIC NAME: Houston Reproductive Center (formerly West Houston Fertility Center)
ADDRESS: 1615 Hillendahl
Houston Texas 77055

CONTACT PERSON: Ann Prunty RN or Dr Ivor S[illegible] MD
PHONE NUMBER: 13 932-5679 713-465-9590

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? one

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
   - (a) Physicians 1
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 1
   - (h) Secretaries ______
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 4 (-1yr it was closed)

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1984 GIFT 1985

9. How many different patients were stimulated?
1987 IVF 1 1988 IVF 19
GIFT 4 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 2 1988 IVF 21
GIFT 4 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 6 1988 16

How many embryo transfer cycles were performed?
1987 1 1988 2

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 4 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ ___% 1988 ___ ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF 17 73%
GIFT 1 ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 0 %
GIFT ___ ___% GIFT 0 %
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 5 24%
GIFT 1 ___% GIFT 0 ___%
(d) Unexplained infertility:
1987 IVF 1 ___% 1988 IVF 5 24%
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): 1 Anovulation + Cervical stenosis
1987 IVF 1 ___% 1988 IVF ___ ___%
1° ovarian failure 4 GIFT 3 ___% GIFT 1 1%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF 10 45%
GIFT 3 50% GIFT 1 ___%
(b) 31-35:
1987 IVF 1 ___% 1988 IVF 9 40%
GIFT ___ ___% GIFT ___ ___%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF 7 17%
GIFT 2 ___% GIFT ___ ___%

(d) 41-45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT 1 ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 5
GIFT 0 GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 4
GIFT 0 GIFT ___

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ___
GIFT ___ ___% ___

1988 IVF ___ ___% ___
GIFT ___ ___% ___

21. What are the qualifications of the director of the embryo laboratory? Embryologist 3 yrs Bourn Hall Clinic, Dept Physiology, Cambridge Eng. IVF Consultant Humana Wellington, London; BS in Biochemistry, M.S. in Reproductive physiology, PhD male Infertility & IVF Erasmus Univ. Rotterdam, Holland. Asst. Prof Dept OB Gyn Emory Univ. (Dr J Cohen see attached)

22. Who supervises the laboratory director? Dr Wm Hall - Director of Lab of Hospital [illegible]

23. Does the clinic participate in an external laboratory proficiency testing program? yes
If the answer is yes, please specify which program.
CAP

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Dr J Cohen @ Emory Univ

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists ____
    (d) Nurses ______
    (e) Other (explain) _______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The Center was closed early 1987 because we were unsuccessful. In 1988 we became affiliated with RBA of Atlanta, Ga with Dr Jacques Cohen PhD as embryologist and have had two cycles with 18 patients completely stimulated ē retrieval and transfer except for one ē Cryo only. Of these 5 have become pregnant - first one due in March 1989. Eight patients have embryos in the freezer

IVF/GIFT SURVEY

CLINIC NAME: Center for Reproductive Medicine
ADDRESS: 8100 Fredericksburg Road
San Antonio, Texas

CONTACT PERSON: David L. Olive, M.D.
PHONE NUMBER: (512) 567-4938

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? Sept, 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based ______
   - (d) Other (explain) Med Sch - Community Hospital Cooperative

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? Four

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? Four

6. How many other professionals participate in your clinic?
   - (a) Physicians 6
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 3
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) Billing Clerk

7. How many years has your infertility clinic been in operation? 2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF August, 1986 GIFT September, 1986

9. How many different patients were stimulated?
1987 IVF 31 1988 IVF 52
GIFT 18 GIFT 10

10. How many stimulation cycles were performed?
1987 IVF 40 1988 IVF 63
GIFT 26 GIFT 10

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 34 1988 56

How many embryo transfer cycles were performed?
1987 36* 1988 54
*2 donor embryo transfers

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 23 1988 9

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0 % 1988 0 ___ %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 26 84 % 1988 IVF 42 91 %
GIFT 0 0 % GIFT 2 20 %
(b) Endometriosis:
1987 IVF 4 13 % 1988 IVF 3 7 %
GIFT 3 17 % GIFT 1 10 %
(c) Male infertility:
1987 IVF 4 13 % 1988 IVF 16 35 %
GIFT 8 44 % GIFT 5 50 %
(d) Unexplained infertility:
1987 IVF 1 3 % 1988 IVF 1 2 %
GIFT 2 11 % GIFT 2 20 %
(e) Other (explain): Luteal phase defect, anovulation, uterine factor,
1987 IVF 4 13 % 1988 IVF 15 33 % cervical factor,
GIFT 12 67 % GIFT 6 60 % antisperm antibodies

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 8 26 % 1988 IVF 17 33 %
GIFT 5 28 % GIFT 3 30 %
(b) 31-35:
1987 IVF 14 45 % 1988 IVF 17 33 %
GIFT 9 50 % GIFT 4 40 %
(c) 36-40:
1987 IVF 8 26 % 1988 IVF 15 29 %
GIFT 4 22 % GIFT 3 30 %

(d) 41-45:
1987 IVF 1 3 % 1988 IVF 3 6 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 1 1988 IVF 11
GIFT 4 GIFT 2

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 5
GIFT 0 GIFT 2

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 3
GIFT 2 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 %
GIFT 0 0 %

1988 IVF 3 100% Twins
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? Ph.D. - Reproductive Physiology; four year postdoctoral fellowship training in IVF at Mayo Clinic under direction of G. David Ball, Ph.D.

22. Who supervises the laboratory director? Medical Director

23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
Irvine Scientific Media Testing

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?

(a) Physicians 2
(b) Laboratory scientists (PhDs) 0
(c) Embryo laboratory technicians/technologists 2
(d) Nurses 3
(e) Other (explain) --

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Our Center for Reproductive Medicine or CRM performs a broad range of assisted reproductive technologies by drawing upon the varied resources made available through a cooperative arrangement between the Department of Ob/Gyn at the U.T.H.S.C.-SA and Humana Women's Hospital-South Texas. In addition to IVF and GIFT procedures, the CRM performs the various laboratory tests (e.g. egg penetration and anti-sperm antibody assays) currently used for the diagnosis of infertility disorders. Also, the CRM maintains a frozen semen repository for therapeutic donor insemination procedures and banking of patient's semen for future use. Patients in the IVF/GIFT program are provided the option of embryo freezing which has to date resulted in two pregnancies with one child born and the other expected (currently 6 months gestation). Since the inception of the CRM roughly 250 patients per year have been treated for infertility with various strategies that have resulted in 188 total pregnancies and 101 births. Proportionately, the number of patients treated with IVF/GIFT represents a low percentage of the total number of patients treated at the CRM because it is the philosophy of our clinic to fully exhaust every other form of infertility treatment of the couple before resorting to the relatively expensive, emotionally and physically draining IVF/GIFT procedures.

IVF/GIFT SURVEY

CLINIC NAME: Dept. Obstetrics & Gynecology - Fertility Center Office
ADDRESS: 50 N. Medical Drive
Salt Lake City, UT 84132
UNIVERSITY OF UTAH

CONTACT PERSON: Kirtly Parker Jones, M.D.
PHONE NUMBER: (801) 581-4837

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 10/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 3(fertility lab)
   - (f) Radiology (Ultrasound) Technicians 3
   - (g) Psychologists/Counselors 1
   - (h) Secretaries ______
   - (i) Other (specify) 1 (Administrative Assistant)

7. How many years has your infertility clinic been in operation? 5 1/2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 3/83 GIFT 5/86

9. How many different patients were stimulated?
1987 IVF 75 1988 IVF 88
GIFT 13 GIFT 8

10. How many stimulation cycles were performed?
1987 IVF 96 1988 IVF 104
GIFT 18 GIFT 9

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 79 1988 86

How many embryo transfer cycles were performed?
1987 72 1988 80

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 13 1988 8

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0 % 1988 ___ 0 % (IVF clinical protocol has been reviewed by IRB)

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 20 25 % 1988 IVF 24 28%
GIFT 1 8 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 6 7 % 1988 IVF 9 10 %
GIFT 4 31 % GIFT 5 62 %
(c) Male infertility:
1987 IVF 12 15 % 1988 IVF 15 18 %
GIFT 0 0 % GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 14 18 % 1988 IVF 13 15 %
GIFT 4 31 % GIFT 3 38 %
(e) Other (explain): multiple factors
1987 IVF 28 35 % 1988 IVF 25 29 %
GIFT 4 30 % GIFT 0 0 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 26 33 % 1988 IVF 27 31 %
GIFT 4 31 % GIFT 3 38 %
(b) 31-35:
1987 IVF 36 46 % 1988 IVF 36 42 %
GIFT 7 54 % GIFT 3 38 %
(c) 36-40:
1987 IVF 14 18 % 1988 IVF 20 23 %
GIFT 2 15 % GIFT 1 12 %

(d) 41-45:
1987 IVF 3 3 % 1988 IVF 3 4 %
GIFT 0 0 % GIFT 1 12 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 17 1988 IVF 28
GIFT 5 GIFT 3

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 12 1988 IVF 9
GIFT 4 GIFT 2

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 15
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 2 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 15 % 2 sets of twins
GIFT 1 25 % 1 set of twins

1988 IVF 5 33 % 5 sets of twins (2 ongoing)
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? Ph.D. Reproductive Physiology, Andrologist, 16 years full time Infertility experience, >50 fertility publications, full professor, active in many reproductive societies

22. Who supervises the laboratory director? Reproductive Endocrinologists, Chairman Division of Urology

23. Does the clinic participate in an external laboratory proficiency testing program? We have created our own national program
If the answer is yes, please specify which program.
No other program is qualified to do reproductive laboratories

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? will be soon

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? Yes

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** Yes

27. **Does the clinic train individuals in IVF or GIFT?** Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    - **(a) Physicians** 5
    - **(b) Laboratory scientists (PhDs)** 1
    - **(c) Embryo laboratory technicians/technologists** 6
    - **(d) Nurses** 8
    - **(e) Other (explain)** Organized National fertility laboratory training program

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**
The University of Utah Fertility Center program, nestled in the Wasatch Mountains, draws patients from a large geographic area primarily throughout the Intermountain West region. Our patient population has proportionately less tubal factor infertility, with a greater percent male factor. The center is staffed with senior level people who have had extensive training and experience with all aspects of fertility and spend full time with infertility problems. The center staff is small enough to ensure personal patient contact and the modern, comfortable facilities provide a compatible environment to the sensitivities of fertility problems. All reasonable fertility treatments are available at success rates comparable to clinics anywhere, including ongoing pregnancies from embryo cryopreservation, and at the lowest feasible cost. We would be delighted to help you in any way possible.

IVF/GIFT SURVEY

CLINIC NAME: University Associates in Ob/Gyn
ADDRESS: Divsion of Reproductive Endocrinology
University of Vermont College of Medicine
Burlington, VT 05405

CONTACT PERSON: Mark Gibson, M.D.
PHONE NUMBER: (802) 656-2272

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ________
   - (b) Community hospital based ________
   - (c) University based XX
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? three

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? three

6. How many other professionals participate in your clinic?
   - (a) Physicians three
   - (b) Laboratory Scientists (PhDs) one
   - (c) Nurses threee
   - (d) Embryo Lab Technicians/Technologists one
   - (e) Other Lab Technicians/Technologists one
   - (f) Radiology (Ultrasound) Technicians none
   - (g) Psychologists/Counselors one
   - (h) Secretaries one
   - (i) Other (specify) 12 Resident Physicians

7. How many years has your infertility clinic been in operation? ten

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 5/86 GIFT 3/86

9. How many different patients were stimulated?
1987 IVF 9 1988 IVF 6
GIFT 1 GIFT 0

10. How many stimulation cycles were performed?
1987 IVF 12 1988 IVF 7
GIFT 1 GIFT 0

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 7 1988 5

How many embryo transfer cycles were performed?
1987 9 1988 6

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 0

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0 % 1988 0 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 4 44 % 1988 IVF 2 33 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 2 22 % 1988 IVF 1 17 %
GIFT 0 0 % GIFT 0 0 %
(c) Male infertility:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 1 100% GIFT 0 0 %
(d) Unexplained infertility:
1987 IVF 3 33 % 1988 IVF 3 50 %
GIFT 0 0 % GIFT 0 0 %
(e) Other (explain): ____________________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 1 11 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %
(b) 31-35:
1987 IVF 6 66 % 1988 IVF 3 50 %
GIFT 0 0 % GIFT 0 0 %
(c) 36-40:
1987 IVF 2 22 % 1988 IVF 2 33 %
GIFT 1 100 % GIFT 0 0 %

(d) 41-45:
1987 IVF 0 0 % 1988 IVF 1 17 %
GIFT 0 0 % GIFT 0 0 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 0 %
GIFT 0 0 %

1988 IVF 0 0 %
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? M.D., Ph.D., with expertise in tissue and cell culture

22. Who supervises the laboratory director? Director of Reproductive Endocrinology - Mark Gibson

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians three
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 0
    (d) Nurses 0
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

We serve as the primary Reproductive Endocrinology & Infertility clinic for a large area which includes Vermont and upstate New York. The nearest referral center which has an established IVF program is 250 miles away (Connecticut or Boston). While we encourage patients suitable for IVF/GIFT to attend a more successful program, we also feel it is important to offer the service as long as we are honest about our programs limitations. Many of our patients would rather undergo this intense and often disappointing experience in a familiar and caring atmosphere than attend an unknown clinic. In helping couples resolve their infertility, either with or without pregnancy, we believe a humane and sensitive approach is a key element in the process.

IVF/GIFT SURVEY

CLINIC NAME: University of Virginia - IVF/GIFT Program
ADDRESS: University of Va. Health Sciences Center
Department of OB/GYN
Division of Reproductive Endocrinology, Box 387
Charlottesville Va 22908
CONTACT PERSON: Bonnie Reilly RN
PHONE NUMBER: 804 924-0312

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/13/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   - (a) Physicians ______
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 1
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists ______
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors ______
   - (h) Secretaries ______
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 2 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 10/86 GIFT 3/87

9. How many different patients were stimulated?
1987 IVF 7 1988 IVF 3
GIFT 3 GIFT 10

10. How many stimulation cycles were performed?
1987 IVF 8 1988 IVF 3
GIFT 4 GIFT 10

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 8 1988 3

How many embryo transfer cycles were performed?
1987 8 1988 2

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 4 1988 6

13. What were the number and percentage of patients on IRB approved research protocols?
1987 ___ 0% 1988 ___ 0%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 6 87.5%* 1988 IVF 3 100% *
GIFT 0 0% GIFT 0 0%
(b) Endometriosis:
1987 IVF 3 37.5%* 1988 IVF 1 33%*
GIFT 2 50% GIFT 4 40%
(c) Male infertility:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 0 0%
(d) Unexplained infertility:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 2 50% GIFT 5 50%
(e) Other (explain): uterine leiomyomatosis
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT 1 10%

* >100% 2° individuals c̄ multiple factors

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 0% 1988 IVF 1 33%
GIFT 0 0% GIFT 2 20%
(b) 31-35:
1987 IVF 1 12.5% 1988 IVF 1 33.3%
GIFT 1 25% GIFT 5 50%
(c) 36-40:
1987 IVF 7 87.5% 1988 IVF 1 33.3%
GIFT 3 75% GIFT 3 30%

(d) 41-45:
1987 IVF ___ 0 % 1988 IVF ___ 0 %
GIFT ___ 0 % GIFT ___ 0 %

(e) >45:
1987 IVF ___ 0 % 1988 IVF ___ 0 %
GIFT ___ 0 % GIFT ___ 0 %

16. How many clinical pregnancies were produced?
1987 IVF 1 1988 IVF 1
GIFT 0 GIFT 2

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0 (1 due Christmas Day)
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT 0 GIFT 2

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% 0
GIFT ___ ___% 0

1988 IVF ___ ___% 0
GIFT ___ ___% 0

21. What are the qualifications of the director of the embryo laboratory? * please see attached sheet

22. Who supervises the laboratory director? Bruce G Bateman M.D Director IVF/GIFT Program

23. Does the clinic participate in an external laboratory proficiency testing program? * please see attached sheet
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? YES

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? NO

27. Does the clinic train individuals in IVF or GIFT? NO
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

University of Virginia
School of Medicine
Charlottesville, Virginia 22908

Department of Obstetrics
and Gynecology

(804) 924-2221
Box 387

December 12, 1988

Congressman Ron Wyden
Suite 1406
Longworth House Office Building
Congress of the United States
Washington, D.C. 20515

Dear Congressman Wyden,

Your efforts to review the state of infertility treatment, including in vitro fertilization (IVF), in this country are welcomed, not only by the patients who seek this treatment, but also by the programs who strive to give the highest quality health care in this area. We are anxious to help in any way we can. I am writing, as head of the IVF lab, to clarify our responses to questions 21 and 23 of your questionaire.

Question 21. What are the qualifications of the director of the IVF laboratory?

The director of this program has: (1) a Ph.D. in biology (1984) in which the focus of training centered on the process of mammalian fertilization, (2) published full-length papers in this and closely related areas of research, (3) acquired on site training over six days at an established IVF center at the University of North Carolina, (4) participated in a 1988 post-graduate workshop in "Advanced Techniques in IVF" sponsored by the American Fertility Society, (5) attended a "Workshop in Cryopreservation" conducted in 1986 by an international authority in embryo cryopreservation, and (6) active memberships in the American Fertility Society and the Society for the Study of Reproduction.

Question 23. Does the clinic participate in an external proficiency testing program?

We are not exactly certain of what is meant by external proficiency testing program. We know of no formally organized review or testing body. We have, however, invited three internationally acclaimed experts in both the clinical and laboratory aspects of IVF to evaluate our program during on site visitations. These evaluations, from Drs. Don Wolf, Gary Hogden, and David Meldrum, have been extremely valuable in determining the proficiency of our program.

In terms of testing, however, we rely primarily on our in house program of quality control. We utilize several bioassays in our quality control efforts, including the accepted

IVF/GIFT SURVEY

CLINIC NAME: Jones Institute for Reproductive Medicine
ADDRESS: Eastern Virginia Medical School
825 Fairfax Avenue - 6th Floor
Norfolk, Virginia 23507

CONTACT PERSON: Dr. Suheil J. Muasher
PHONE NUMBER: (804) 446-8948

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/31/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 4 (5 as of 7/1/89)

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 4

6. How many other professionals participate in your clinic?
   - (a) Physicians 8 staff; 5 fellows
   - (b) Laboratory Scientists (PhDs) 7
   - (c) Nurses 5
   - (d) Embryo Lab Technicians/Technologists 5
   - (e) Other Lab Technicians/Technologists 3
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 12
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 10 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1981 GIFT 1986

9. How many different patients were stimulated?
1987 IVF 500 1988 IVF 560
GIFT 1 GIFT 2

10. How many stimulation ~~cycles~~ attempts were performed?
1987 IVF 737 1988 IVF 783
GIFT 1 GIFT 2

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 637 1988 705

How many embryo transfer cycles were performed?
1987 573 1988 636

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 2

13. What were the number and percentage of patients on IRB approved research protocols?
1987 738 100 % 1988 785 100 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 397 53.8% 1988 IVF 410 52.2 %
GIFT 1 .01 % GIFT 1 0.01 %
(b) Endometriosis:
1987 IVF 69 9.3 % 1988 IVF 62 7.9 %
GIFT - - % GIFT - - %
(c) Male infertility:
1987 IVF 113 15.3% 1988 IVF 194 24.7%
GIFT - - % GIFT - - %
(d) Unexplained infertility:
1987 IVF 31 4.2 % 1988 IVF 15 1.9 %
GIFT - % GIFT - - %
(e) Other (explain): Cervical, DES, Anov, Immuno, + cancelled without Diag Code
1987 IVF 127 17.0% 1988 IVF 102 12.9 %
GIFT - - % GIFT 1 0.01 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 74 10 % 1988 IVF 90 11.5 %
GIFT - - % GIFT - - %
(b) 31-35:
1987 IVF 311 42.1 % 1988 IVF 313 39.9 %
GIFT 1 .01 % GIFT 1 0.01 %
(c) 36-40:
1987 IVF 325 44 % 1988 IVF 342 43.6%
GIFT - - % GIFT - - %

(d) 41-45:
1987 IVF 27 3.6 % 1988 IVF 38 4.8 %
GIFT - - ___ % GIFT ___ ___ %

(e) >45:
1987 IVF 0 ___ % 1988 IVF 0 ___ %
GIFT 0 ___ % GIFT 0 ___ %

16. How many clinical pregnancies were produced?
1987 IVF 145 1988 IVF 146
GIFT 0 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 106 1988 IVF 21
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 88
GIFT 0 GIFT 1

19. How many ectopic pregnancies resulted?
1987 IVF 5 1988 IVF 4
GIFT - GIFT -

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 22 20.7% 20 twins; 1 triplet; 1 quadruplet
GIFT ___ ___ % ___

1988 IVF 20 18.0% 4 twins: delivered (15 twins ongoing;
GIFT ___ ___ % 1 quadruplet in progress)

21. What are the qualifications of the director of the embryo laboratory? Eight years as director. Author of "Atlas of Human Oocyte and Early Conceptus" Williams and Wilkins 1986

22. Who supervises the laboratory director? Program Director

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 50+ (Estimates)
    (b) Laboratory scientists (PhDs) 25+
    (c) Embryo laboratory technicians/technologists 25+
    (d) Nurses 10
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Please see attached sheets.

28.

We would like to emphasize that general statistics may not apply to an individual patient. Success rates vary, depending on many factors such as patient age, cause of infertility, endocrinologic status, adequacy of stimulation, number and maturity of the oocytes retrieved, success or failure of fertilization and cleavage in vitro, and adequacy of the luteal phase after embryo transfer. In Norfolk, using patients' blood levels of serum FSH and LH on cycle day 3, we have established that patients belong to different groups which yield variable results in stimulation quality, number and quality of oocytes obtained, and pregnancy rates. Based on these blood levels, certain groups of patients can have a pregnancy rate >30%, while others yield a low pregnancy rate of <10%.

During the last two years, the pregnancy rates/transfer have been >30% for patients <40 years of age with normal basal gonadotropin levels (excluding male factor patients) and >35% for patients with unexplained (idiopathic), immunologic, and anovulatory infertility (common indication for the GIFT procedure) after IVF treatment.

Proper identification of patients with a poor success rate is essential for counseling and for adjustments in stimulation protocols to yield better results. For example, during the last two years the addition of gonadotropin-releasing hormone agonist (commercially available as Lupron) to the stimulation regimen in certain groups of patients has allowed us to achieve a live birth rate (the number of women delivering babies/the number of women undergoing treatment) of >20%. Another example is the patient with an extremely low success rate (who usually has a serum FSH level >20 mIU/ml on cycle day 3), in whom stimulation quality and success rates can be improved by special stimulation protocols. Thus, it is to be emphasized that we counsel patients on an individual basis and administer stimulation protocols that best fit the patient's existing hormonal and physiologic stimulation.

Another factor which can influence success rates is the male factor. Using semen analysis and other tests in our laboratory, we have identified a certain group of patients who have a low success rate after IVF treatment. These patients are offered a variety of therapeutic modalities to improve their success rates. Micromanipulation techniques, such as sperm microinjection (in cases with severe sperm abnormalities and prior failed fertilization), are offered to patients in our program according to approved research protocols.

Oocyte retrieval is performed almost exclusively by ultrasound-guided transvaginal aspiration under local anesthesia. Laparoscopy is needed for the GIFT procedure.

We have an active embryo cryopreservation program in our unit. Because we currently limit transfers to three or four fertilized preovulatory oocytes, excess pre-embryos can be cryopreserved. This limits the number of multiple pregnancies and offers added chances for the patient to become pregnant from each stimulated cycle. The cost of transferring cryopreserved embryos is markedly less than a full IVF treatment cycle, offering another advantage to the patient. We have had 22 clinical pregnancies in 87 transfers of frozen/thawed pre-embryos. These pregnancies were not included in the pregnancy figures provided for 1987 and 1988.

Our program is active in basic and clinical research. All results of this research, as well as clinical IVF data, are published in peer review journals.

IVF/GIFT SURVEY

CLINIC NAME: Medical College of Virginia
ADDRESS: Box 34, MCV Station
Richmond, VA 23298

CONTACT PERSON: Cathy James, R.N., Nurse Coordinator
PHONE NUMBER: (804) 786-9638

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/13/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ______
   - (c) University based X
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2 with 1 Board Eligible

6. How many other professionals participate in your clinic?
   - (a) Physicians 3
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 5
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians ______
   - (g) Psychologists/Counselors ______
   - (h) Secretaries 1
   - (i) Other (specify) Psychiatrist - 1

7. How many years has your infertility clinic been in operation? 2

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF November 1986 GIFT August 1988

9. How many different patients were stimulated?
1987 IVF 24 1988 IVF 30
GIFT ___ GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 43 1988 IVF 33
GIFT ___ GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 26 1988 30

How many embryo transfer cycles were performed?
1987 24 1988 28

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 ___ 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

*14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 16 66 % 1988 IVF 18 6 %
GIFT ___ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF 1 4 % 1988 IVF 5 17 %
GIFT ___ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF 2 8 % 1988 IVF 7 23 %
GIFT ___ ___% GIFT 1 100 %
(d) Unexplained infertility:
1987 IVF 5 21 % 1988 IVF 5 17 %
GIFT ___ ___% GIFT ___ ___%
(e) Other (explain): ___
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 5 21 % 1988 IVF 7 23 %
GIFT ___ ___% GIFT ___ ___%
(b) 31-35:
1987 IVF 8 33 % 1988 IVF 11 37 %
GIFT ___ ___% GIFT 1 100%
(c) 36-40:
1987 IVF 10 42 % 1988 IVF 12 40 %
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF 1 4 % 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

** 16. How many clinical pregnancies were produced?
1987 IVF 8 1988 IVF 10
GIFT ___ GIFT ___

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 1 1988 IVF 10
GIFT ___ GIFT ___

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 6
GIFT ___ GIFT ___

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF 1
GIFT ___ GIFT ___

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% ___
GIFT ___ ___% ___ ___

1988 IVF 1 10 % Twins
GIFT ___ ___% ___

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Zoology and Anatomy. Post doctoral training at UCLA with IVF experience.

22. Who supervises the laboratory director? Leo J. Dunn, M.D.
Chairman

23. Does the clinic participate in an external laboratory proficiency testing program? Yes, for LH, FSH & E_2, RIA
If the answer is yes, please specify which program.
ENDO - Washington, D.C. Wellcome - England

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Application pending

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

* 14. Due to multiple factors, there appears to be more patients treated than listed in Question #9.

** 16. Our definition of clinical pregnancy is: "a gestational sac with cardiac movement," however one of the clinical pregnancies reported has not yet had the ultrasound examination.

In addition to the above information, we have performed 6 cycles transferring cryopreserved embryos. We have one pregnancy, 22 weeks gestation, from this technique. We also have transferred donor oocytes into two different women. One woman is currently pregnant.

RECEIVED
NOV 28 1988
Hon. Ron Wyden

IVF/GIFT SURVEY

CLINIC NAME: Henrico Doctors Hospital / Richmond Center for Fertility and Endocrinology, Ltd.
ADDRESS: 7605 Forest Ave, Suite 207
Richmond Va 23229

CONTACT PERSON: Sue C Wood RNC, MS, CANP
PHONE NUMBER: (804) 285-9700

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/15/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 2

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? (Same 2)

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2 (+ operating room personnel)
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 2 *
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 1 *
   - (h) Secretaries 3*
   - (i) Other (specify) 0

* may have other duties outside IVF program

7. How many years has your infertility clinic been in operation? 4½ years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 5/84 GIFT 1/86

9. How many different patients were stimulated?
1987 IVF 17 1988 IVF 28
GIFT 10 GIFT 17

10. How many stimulation cycles were performed?
1987 IVF 21 1988 IVF 38
GIFT 12 GIFT 17

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 14 1988 30

How many embryo transfer cycles were performed?
1987 13 1988 28

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 11 1988 16

13. What were the number and percentage of patients on IRB approved research protocols?
1987 NA 0 % 1988 NA 0 %

14. What were the number and percentage of patients treated for:

★ Some categories reported twice (due to multiple diagnoses in same patient)

(a) Tubal factor
1987 IVF 9 53 % 1988 IVF 13 46 %
GIFT 0 0 % GIFT 0 0 %
(b) Endometriosis:
1987 IVF 5 29 % 1988 IVF 9 32 %
GIFT 4 40 % GIFT 10 59 %
(c) Male infertility:
1987 IVF 4 29 % 1988 IVF 19 76 %
GIFT 3 33 % GIFT 7 41 %
(d) Unexplained infertility:
1987 IVF 2 12 % 1988 IVF 0 0 %
GIFT 7 70 % GIFT 4 24 %
(e) Other (explain): Polycystic ovaries; ovulatory failures; DES anomalies
1987 IVF 1 7 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 4 24 %
Serum antibodies

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 5 29 % 1988 IVF 7 25 %
GIFT 1 10 % GIFT 5 29 %
(b) 31-35:
1987 IVF 4 24 % 1988 IVF 10 36 %
GIFT 3 33 % GIFT 4 24 %
(c) 36-40:
1987 IVF 7 41 % 1988 IVF 11 39 %
GIFT 6 60 % GIFT 8 47 %

(d) 41-45:
1987 IVF 1 6 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 0 0 %
GIFT 0 0 % GIFT 0 0 %

16. How many clinical pregnancies were produced?
1987 IVF 5 1988 IVF 7
GIFT 3 GIFT 6

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 5 1988 IVF 4
GIFT 3 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 4
GIFT 0 GIFT 4

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 1 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 40 % (TWINS - 1set) (Quads - 1 set)
GIFT 1 33 % TWINS - 1set

1988 IVF 2 50 % (TWINS - 2 sets)
GIFT 0 0 %

21. What are the qualifications of the director of the embryo laboratory? PhD. extensive Research experience in Mouse IVF System, Founded IVF Lab at Medical College of Virginia 1978, Director, IVF LAB and ANDROLOGY CENTER at Present Hospital.

22. Who supervises the laboratory director? Program Director; S. Rosenberg, MD

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? YES

27. Does the clinic train individuals in IVF or GIFT? NO
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Not necessary to Publish

We are dedicated to providing professional, quality IVF and GIFT care, and fully support the efforts of S.A.R.T. to provide "quality control". Our patients are not restricted by age or diagnosis, and our pregnancy ~~success~~ ~~[illegible]~~ statistics include all categories of patients.

IVF/GIFT SURVEY

CLINIC NAME: REPRODUCTIVE GENETICS LABORATORY
ADDRESS: SWEDISH HOSPITAL MEDICAL CENTER
747 SUMMIT AVENUE
SEATTLE, WA. 98104

CONTACT PERSON: MARY S. FORSTER, Ph.D.
PHONE NUMBER: (206) 386-2483

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 9/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? NONE

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 7

6. How many other professionals participate in your clinic?
   - (a) Physicians 1
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 6
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 0
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 2
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 4

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF Jan, 1984 GIFT August, 1985

9. How many different patients were stimulated?
1987 IVF 81 1988 IVF 124
GIFT 158 GIFT 93

10. How many stimulation cycles were performed?
1987 IVF 102 1988 IVF 145
GIFT 204 GIFT 101

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 80 1988 112

How many embryo transfer cycles were performed?
1987 68 1988 95

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 137 1988 75

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 56 88% 1988 IVF 58 64%
GIFT 22 17 % GIFT 15 20 %
(b) Endometriosis:
1987 IVF 4 6% 1988 IVF 15 17 %
GIFT 39 30 % GIFT 22 29 %
(c) Male infertility:
1987 IVF 2 3% 1988 IVF 8 9 %
GIFT 44 34 % GIFT 20 27 %
(d) Unexplained infertility:
1987 IVF 1 2 % 1988 IVF 7 8 %
GIFT 12 9 % GIFT 12 16 %
(e) Other (explain): Polycystic Ovaries, Ovulatory Dysfunctio
1987 IVF 1 2 % 1988 IVF 2 2 %
GIFT 12 9 % GIFT 6 8 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 13 16% 1988 IVF 21 16 %
GIFT 32 20 % GIFT 17 18 %
(b) 31-35:
1987 IVF 38 46% 1988 IVF 46 37%
GIFT 61 38 % GIFT 35 37 %
(c) 36-40:
1987 IVF 24 29% 1988 IVF 41 33%
GIFT 54 34 % GIFT 30 32 %

(d) 41-45:
1987 IVF 6 7 % 1988 IVF 14 11 %
GIFT 9 5 % GIFT 10 10 %

(e) >45:
1987 IVF 0 0 % 1988 IVF 2 1 %
GIFT 2 1 % GIFT 1 1 %

16. How many clinical pregnancies were produced?
1987 IVF 10 1988 IVF 20
GIFT 26 GIFT 24

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 7 1988 IVF 9
GIFT 34 GIFT 13

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 12
GIFT 0 GIFT 14

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 2 GIFT 2

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 28 % Both Twins
GIFT 8 23 % 7 twins, 1 triplets

1988 IVF 1 11 % Quadruplets
GIFT 4 28 % All Twins

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Reproductive Physiology with experience in mechanism of action of Reproductive Hormones, male infertility testing and animal in vitro fertilization.

22. Who supervises the laboratory director? Laurence E. Karp, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? no
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? YES

26. Is the clinic a member of the Society for Assisted Reproductive Technology? NO

27. Does the clinic train individuals in IVF or GIFT? Upon request
If the answer is yes, how many individuals in the following specialties have been trained?
- **(a) Physicians** ________
- **(b) Laboratory scientists (PhDs)** 1
- **(c) Embryo laboratory technicians/technologists** 1
- **(d) Nurses** ________
- **(e) Other (explain)** ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Many of the patients treated through this laboratory have at least two indications for IVF or GIFT procedures. Eighty of the IVF patients (24%) had at least two indications for the procedure and 145 of the GIFT patients (47%) had at least two indications for the procedure.

Patients in this clinic are not always cancelled when their cycles are not good. This is especially true if a patient has tried several different stimulation protocols or repeated cycles and responds marginally to these different stimulations. The situation is explained to the patients and they may decide to proceed, knowing there is a decreased chance of success. This is done only with marginal responders, not with extremely poor responders. Pregnancies have resulted in this group but it is at a lower rate.

Several questions in the survey are not definitive in what they ask. Question 14 asks the number of patients treated with either IVF or GIFT for 5 different indications. The data, therefore, are based on the number of different patients who were treated, or had embryos or gametes replaced. The percentage calculated is based on this total number.
Questions 15 asks the number of patients in different age groups and does not ask the number of patients treated in each. The data for this, therefore, are based on the total number of different patients stimulated.
Questions 17 asks the number of women who delivered live infants in 1987 so this includes women who became pregnant via IVF/GIFT in the last nine months of 1986.

This laboratory serves as the IVF laboratory for several private physicians. All procedures are performed according to common protocols. The data presented here are the combined results from these physicians. Some of the affiliated physicians may wish to report their results separately from these combined results.

IVF/GIFT SURVEY

CLINIC NAME: University of Washington
ADDRESS: Special Fertility Programs
Dept. OB/GYN, RH-20
University Hospital
Seattle, WA 98195
CONTACT PERSON: Paul W. Zarutskie, M.D.
PHONE NUMBER: 206/543-0670 (Office)
548-4071 (IVF Program)

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 11/1/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ____
   (b) Community hospital based ____
   (c) University based X
   (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 3

6. How many other professionals participate in your clinic?
   (a) Physicians 3
   (b) Laboratory Scientists (PhDs) 2
   (c) Nurses 2
   (d) Embryo Lab Technicians/Technologists 2
   (e) Other Lab Technicians/Technologists 2
   (f) Radiology (Ultrasound) Technicians 3
   (g) Psychologists/Counselors 2
   (h) Secretaries 2
   (i) Other (specify) Patient Care Coordinator - 1
   Clinical Assistant - 1 MD's Assistant-1

7. How many years has your infertility clinic been in operation? 4

8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 1984 GIFT 1987

9. How many different patients were stimulated?
1987 IVF 133 1988 IVF 152
GIFT 9 GIFT 6

10. How many stimulation cycles were performed?
1987 IVF 175 1988 IVF 195
GIFT 10 GIFT 6

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 134 1988 139

How many embryo transfer cycles were performed?
1987 122 1988 123

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 7 1988 5

13. What were the number and percentage of patients on IRB approved research protocols?
1987 17 10 % 1988 0 ___ %

14. What were the number and percentage of patients treated for:
(a) Tubal factor: 69
1987 IVF 121 69 % 1988 IVF 129 66 %
GIFT 0 ___ % GIFT 0 ___ %
(b) Endometriosis:
1987 IVF 13 7 % 1988 IVF 22 11 %
GIFT 1 ___ % GIFT 1 20 %
(c) Male infertility:
1987 IVF 23 13 % 1988 IVF 27 14 %
GIFT 0 ___ % GIFT 0 ___ %
(d) Unexplained Infertility:
1987 IVF 15 9 % 1988 IVF 10 5 %
GIFT 4 ___ % GIFT 3 60 %
(e) Other (explain): Cervical, Ovulatory
1987 IVF 3 1 % 1988 IVF 7 4 %
GIFT 2 ___ % GIFT 1 20 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 51 29 % 1988 IVF 39 20 %
GIFT ___ ___ % GIFT ___ ___ %
(b) 31-35:
1987 IVF 70 40 % 1988 IVF 87 44 %
GIFT ___ ___ % GIFT ___ ___ %
(c) 36-40:
1987 IVF 52 30 % 1988 IVF 63 32 %
GIFT ___ ___ % GIFT ___ ___ %

(d) 41-45:
1987 IVF 2 1 % 1988 IVF 6 3 %
GIFT ___ ___% GIFT ___ ___%

(e) >45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT ___ ___% GIFT ___ ___%

* 16. How many clinical pregnancies were produced?
1987 IVF 22 1988 IVF 17
GIFT 2 GIFT 3

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 16 1988 IVF 10
GIFT 0 GIFT 3

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 12
GIFT 0 GIFT 2

19. How many ectopic pregnancies resulted?
1987 IVF 1 1988 IVF 1
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 7 43.7% 7 sets of twins
GIFT 0 ___%

1988 IVF 5 29.4% 3 sets of twins, 2 sets of triplets
GIFT ___ ___%

21. What are the qualifications of the director of the embryo laboratory? BA, Stanford, 10 yrs experience in embryonic tissue culture laboratories; IVF Technologist for 4 yrs under Frank Kuzan, Ph.D., former IVF Laboratory Director.

22. Who supervises the laboratory director? Paul W. Zarutskie, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.
NO

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? YES

* Clinical Pregnancy Definition: Strict definition of National Registry - ie, ulstrasound documentation of a gestation does not include using HCG only, or ultrasound documentation of desidual reactions.

26. **Is the clinic a member of the Society for Assisted Reproductive Technology?** YES

27. **Does the clinic train individuals in IVF or GIFT?** YES **If the answer is yes, how many individuals in the following specialties have been trained?**
    (a) **Physicians** 28
    (b) **Laboratory scientists (PhDs)** 0
    (c) **Embryo laboratory technicians/technologists** 0
    (d) **Nurses** 4
    (e) **Other (explain)** Satellite IVF Program (as described Below)

28. **Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.**

A cooperative venture between infertility specialists at the University of Washington and private practice physicians in seventeen locations throughout Washington, Alaska, Montana, Idaho, and Western Canada has substantially reduced the expenditure of both patient, time, and money by providing training for community physicians and support staff. Patients eligible for IVF can be identified and initiate their cycles at home and when specific ovarian response criteria are met, the patients come to the university for oocyte recovery and embryo transfer procedures.

The University of Washington IVF Program has developed new reproductive technology procedures. In applying knowledge gained through IVF practice, a nonsurgical alternative to IVF has been established for end stage infertility patients without tubal disease. The super ovulation uterine replacement capacitation and enhancement (SOURCE) program, is based on the assumption that certain women with normal fallopian tubes can become pregnant by appropriately stimulating the ovaries and timing the placement of the prepared semen sample in the uterus; thus avoiding an operative procedure.

Our research emphasis is in treating couples with known male factor infertility. Our laboratory is presently studying improved laboratory testing to assess the ability of the sperm to penetrate the egg. Techniques are also being devised to inject a single sperm on to the surface of the oocyte.

The University of Washington has an active donor oocyte program in which women with premature ovarian failure, or in situations of inadequate ovulation induction, are able to receive embryos that have developed from oocytes donated by a another woman and fertilized in vitro with sperm obtained from the recipients husband.

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In vitro fertilization becomes more accessible for the region's residents.

Sonographic egg recovery and SOURCE give some infertile couples more options.

New technologies expand in vitro fertilization choices.

Women experiencing ovulation failure may be helped by carefully monitored induction.

Comprehensive care for male infertility and impotence includes counseling for couples.

Capacitation and acrosome reaction are key events in fertilization.

Careful screening is essential to protect the health of mother and fetus.

Infertility services at University Hospital and Harborview Medical Center are briefly described.

Synapse is published three times a year by the University of Washington Hospitals for practicing physicians in the Pacific Northwest.

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Seattle, Washington 98195

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MEDCON

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548–6111

In Washington:
1–800–562–7700

In Alaska, Oregon, Montana, Idaho:
1–800–426–7600

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A Seattle-based airborne patient transport service, Airlift Northwest makes specialized critical care accessible to patients throughout the Pacific Northwest. To activate the service, Washington physicians call 1–600–542–1646; physicians outside Washington call 1–800–426–2430.

For more information on Airlift Northwest, contact the ALNW business office at (206) 223–8377.

Marvin Turck, M.D., Medical Director, Harborview Medical Center
Loren C. Winterscheid, M.D., Medical Director, University Hospital

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University Hospital

Harborview Medical Center

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Satellite IVF Program Benefits Patients and Physicians

A cooperative venture between infertility specialists at the University of Washington and private practice physicians in 17 locations throughout Washington, Alaska, Montana, and Idaho (WAMI) is making it easier for physicians in outlying areas to offer in vitro fertilization as an option for their patients who are experiencing infertility.

"The UW Satellite IVF Program centralizes oocyte recovery and embryo transfer, the costliest aspects of IVF," said Dr. Paul Zarutskie, clinical director of the University of Washington IVF Program. "We have substantially reduced the expenditure of both time and money for patients undergoing IVF by providing training for community physicians and support staff so that patients can complete their screening and initiate their cycles at home.

"The satellite program accounts for 25 percent of our total IVF program volume and has achieved a viable pregnancy rate per oocyte recovery procedure of 21 percent, consistent with our university-based IVF program," he added.

As of June 1987, 131 cycles had been initiated in the UW-IVF program; the satellite program accounted for 54 of these cycles. Half of the cycles (27) resulted in patients being referred to the UW for oocyte recovery, and 26 embryos were transferred. Six viable pregnancies resulted.

Community Training

Participating WAMI physicians attend a three-day training program presented by UW infertility specialists at the University of Washington on IVF ovulation induction methods and monitoring techniques. Laboratory and ultrasound monitoring criteria are included.

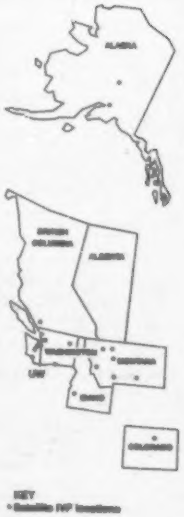
Under the direction of these community physicians, local laboratories contact the UW Department of Laboratory Medicine to set up the estradiol testing necessary in the IVF protocol. This system allows the UW-IVF program to maintain quality control of critical monitoring parameters.

The community physicians involved in the Satellite IVF Program identify and schedule couples eligible as IVF candidates, initiate ovulation induction according to a fixed clomiphene citrate/human menopausal gonadotropin (CC/HMG) protocol, and determine appropriate responses of ovarian stimulation for oocyte recovery.

Cycles are coordinated through the UW-IVF office. If specific ovarian response criteria are met, the patients come to the UW on cycle day 9 for oocyte recovery and embryo transfer procedures. The participating community physicians then assume responsibility for post-procedure follow-up and/or obstetrical care.

To date, 21 physicians in WAMI communities are providing satellite IVF for their patients. Future plans for the program, in addition to incorporating new centers, include additional participant training on alternate ovulation induction methods.

Information on the IVF Program:
Paul W. Zarutskie, M.D.
Clinical Director
(206) 543–0670



Satellite IVF locations include:

- Fairbanks, AK
- Anchorage, AK
- Everett, WA
- Edmonds, WA
- Longview, WA
- Tacoma, WA
- Pasco, WA
- Spokane, WA
- Vancouver, British Columbia
- Kalispell, MT
- Great Falls, MT
- Missoula, MT
- Bozeman, MT
- Billings, MT
- Boise, ID
- Englewood, CO
- Edmonton, Alberta

New Techniques Enhance Infertility Services

Two new non-operative techniques, combined with knowledge gained from research at the University of Washington into biochemical factors related to oocyte and sperm quality, maturation, and activity, are being used successfully with infertility patients at University Hospital.

Sonographic Egg Recovery (SER)

In 1987, the UW-IVF Program began using a new technique known as transvaginal sonographic egg recovery (SER), which combines basic IVF technology with computerized ultrasound imaging to identify and recover oocytes for fertilization.

Use of transvaginal SER as an alternative to laparoscopy was pioneered in Australia a few years ago. The technique involves placing an ultrasound probe into the vagina and guiding an aspirating needle through the vaginal wall and into the ovarian follicles by following the ultrasound image of the needle and follicles on a viewing screen. Fluid is aspirated from the follicles and inspected microscopically for the presence of [illegible].

"SER has several advantages over the standard laparoscopic egg recovery technique," explained Dr. Paul Zarutskie, clinical director of the IVF Program. "Because it is simpler and less expensive, we can proceed to recover only one or two oocytes from women who would otherwise be considered poor candidates for laparoscopic oocyte recovery due to the presence of fewer than three follicles.

"In addition, SER can be performed with local anesthesia in an office setting," he added. "This avoids the general anesthetic necessary for laparoscopic egg recovery, and patients recover completely in less than 30 minutes. And by decreasing the cost of individual cycles using SER, IVF can be made available to more couples."

SOURCE

The Super-Ovulation Uterine Capacitation Enhancement (SOURCE) program is based on the assumption that infertile women with normal fallopian tubes can become pregnant with stimulation and insemination, without resorting to an operative procedure.

It is a non-surgical alternative to the GIFT (gamete intrafallopian transfer) procedure. GIFT involves the direct transfer of preovulatory oocytes and washed sperm into the fallopian tubes, which requires an operation (laparoscopy) and general anesthetic.

The non-operative SOURCE program has four steps:

1. Development of ovarian follicles, using a combination of clomiphene citrate and human menopausal gonadotropin (Pergonal), beginning on day 3 of the patient's menstrual cycle. The medication is used for 6 to 9 days, depending on how ovarian follicular development is progressing. This is monitored by checking daily serum estradiol and LH levels and using pelvic ultrasound.

2. Stimulation of ovulation with human chorionic gonadotropin (HCG) when ultrasound and blood estradiol levels indicate the follicles are mature.

3. Intrauterine insemination with the husband's washed sperm performed each of the two days after the HCG is given.

4. Hormonal support of the luteal phase with progesterone, given intramuscularly until the result of the pregnancy test is known (approximately 14–20 days).

If too many follicles mature at once or if blood estradiol levels are too high, the protocol will shift to a standard IVF procedure with oocyte retrieval. This usually allows greater control over the risk of multiple pregnancies and hyperstimulation. Patients must agree to the possibility of such a transition before a SOURCE cycle can be initiated.

To date, the UW program has shown a pregnancy rate of 25 percent. SOURCE should be used only in infertility programs that offer IVF as a back-up.

Transvaginal sonographic egg recovery (SER), which is simpler and less expensive than laparoscopic egg recovery, makes IVF feasible even for women who develop only one follicle (seen here in an ultrasound image).

Information on SER:
Paul W. Zarutskie, M.D.
Clinical Director, In Vitro Fertilization Program
(206) 543–0670

Information on SOURCE:
Donald E. Moore, M.D.
(206) 543–0670

AIDS Brings New Caution to Therapeutic Donor Insemination Program

Because AIDS and other sexually transmitted diseases can be spread via semen, use of donor insemination as a therapy for infertility must be carefully managed.

The UW Therapeutic Donor Insemination (TDI) program at the University Hospital Women's Care Clinic has switched from fresh semen samples to frozen semen obtained from commercial cryobanks which have stringent criteria to screen donors for genetic, medical, and infectious diseases.

Semen donors are screened by (1) personal interview; (2) medical, reproductive, and genetic history; (3) physical exam; (4) semen analysis and sperm post-thaw survivability; and (5) testing for blood type, Rh factor, hepatitis, AIDS, and other sexually transmissible diseases, including cytomegalovirus, herpes, syphilis, gonorrhea, mycoplasma, trichomonas, and chlamydia.

"It is important not only that the donor, but also his partner, be infection-free," noted Dr. Donald Moore, who directs the UW TDI program. "Both individuals should have a new history taken and be tested for gonorrhea, chlamydia, herpes, cytomegalovirus, and hepatitis every two to three months."

Tests for human immunodeficiency virus (HIV) should be done monthly. Sperm should not be released until the donor has tested negative for HIV for at least three months after the sperm were collected.

Another important consideration is the quality of the sperm. "Ideally, the cryobank should check for post-thaw motility in a small amount of each sample and send a report of these findings along with the sample," Moore said.

Couples in the TDI program are given a list of available donors' characteristics, including height, weight, blood type, eye and hair color, profession, interests, and ethnic origin. The number of pregnancies by each donor is carefully tracked and limited to 10 patients in the UW program.

When fresh semen is used, an average of four cycles of TDI are required for conception to occur and approximately 75 percent of normally fertile women conceive within six cycles. Conception takes about the same amount of time or perhaps a little longer when frozen semen samples are used, and couples are advised to plan as many as six to nine months of inseminations.

Couples choosing to use TDI have many issues to resolve. They need to explore their degree of loss at not being able to continue the husband's genes into the next generation and the loss of the husband's physical characteristics in the child. Couples also should consider their feelings about using an unknown individual's sperm to conceive their child.

In addition, they need to explore their feelings of acceptance of the child—will they be able to accept him or her as their own? Finally, they need to determine with whom they will share the knowledge that they conceived through donor sperm, and also whether to share that information with their future child.

Washington state law requires that the physician file the husband's written consent and date of insemination if a child is born as a result of TDI. The state maintains this record in a sealed file which can only be opened by a court order; the recipient's husband is considered the child's legal father and is listed as such on the birth certificate.

Information on TDI:
Donald E. Moore, M.D
Director, TDI Program
(206) 543–6137

Overview: Infertility Services at the University of Washington Hospitals

University Hospital

Reproductive Endocrinology-Infertility Services
(206) 543–0670

Reproductive endocrinology
Ovulation induction
Tubal microsurgery
Uterine anomalies
Endometriosis
Female androgen excess

Special Infertility Services
(206) 548–4071

In vitro fertilization (IVF)
Super-Ovulation Uterine Capacitation
 Enhancement (SOURCE)
Donor oocyte program (DOP)
Cryopreserved embryo program (CPE)
Therapeutic donor insemination (TDI)
GnRH pump, Pergonal
Sperm penetration assay (SPA)

Michael R. Soules, M.D.
Director, Division of Reproductive Endocrinology

Leon R. Spadoni, M.D.
Vice Chairman, Department of Obstetrics and Gynecology

Paul W. Zarutskie, M.D.
Clinical Director, IVF Program

Donald E. Moore, M.D.
SOURCE and TDI

Frank Kuzan, Ph.D.
Director, IVF Laboratory

Charles H. Muller, Ph.D.
Director, Andrology Laboratory

Harborview Medical Center

Reproductive and Sexual Medicine Clinic
(206) 223–3121

Comprehensive care for male infertility and impotence; treatment of other sexual problems in both men and women.

Jointly operated by the University of Washington School of Medicine (Departments of Urology and of Psychiatry and Behavioral Sciences) and Harborview Medical Center.

Richard E. Berger, M.D.
Julia R. Heiman, Ph.D.
Directors

Events on Cellular Level Affect Male Fertility

What has been missing from the evaluation of infertile couples is a series of tests of human sperm function directed at diagnosing specific processes and defects in the events leading to fertilization, according to Dr. Charles Muller, director, Andrology Laboratory.

Male infertility has traditionally been clinically diagnosed by semen analysis, assessing sperm concentration, morphology, and motility. However, these tests do not encompass all the complex cellular and biochemical conditions necessary for fertilization, such as epididymal maturation, or capacitation and acrosome reaction in the female reproductive tract.

During capacitation the protein molecules on the sperm surface redistribute, and fluidity of the plasma membrane increases, due in part to a loss of membrane cholesterol. The discovery by Muller and graduate student Stuart Ravnik of cholesterol transfer proteins that expedite this process in human female reproductive tract fluids indicates that uterine fluid or follicular fluid around the egg may normally stimulate capacitation.

"The more such molecules that are identified, and the more we know about their role in fertilization, the better we will be able to develop clinical diagnostic tests and therapeutic methods that focus directly on these specific components and events," said Muller.

Capacitation sets up the acrosome reaction, triggered by the zona pellucida. First, calcium levels within the sperm increase by orders of magnitude. Then the sperm plasma membrane and the outer acrosomal membrane fuse, opening holes through which sperm acrosomal enzymes escape to help digest a path through the zona, enabling the sperm to reach the oocyte (Fig. 2).

Sperm Penetration Assay

A major breakthrough in assessing the fertilizing ability of human sperm came in the late 1970s with the development of the zona-free hamster egg penetration assay, or Sperm Penetration Assay (SPA). The SPA measures the ability of human sperm to capacitate and acrosome react, and then to fuse with a zona-free hamster oocyte, in the absence of any human female reproductive tract components. It has proven to be a good, but not perfect, clinical predictor of in vivo fertilization.

In a recently-completed three-year study of couples referred to the UW because of infertility, men whose SPA showed more than 10 percent of oocytes penetrated were found to have a significantly higher probability of impregnating their wives (who had no detected infertility factors) than men in whom the SPA was less than 10 percent (Fig. 1).

"We are trying to improve the accuracy and usefulness of the SPA by incubating sperm under conditions that enhance capacitation or stimulate acrosome reaction," explained Muller. "Where we can, this is accomplished by using components of the female reproductive tract that may be essential for sperm fertilizing ability in vivo."

Muller and Andrology Laboratory clinicians have developed a diagnostic flow-sheet, which leads to several new therapeutic approaches. The first and simplest of these involves timing.

The standard sperm incubation period for SPA is about 20 hours. However, UW infertility researchers have found that more than a third of their male patients have spermatozoa that capacitate and acrosome react within six hours. These sperm are often dead or incapable of penetration 12 hours later. "This finding helps explain 'false negatives' in the standard SPA, and suggests that laboratories should test sperm at both long and short incubation times," Muller said.

When sperm capacitate quickly, the timing of ovulation needs to be carefully monitored or controlled. "We use timed intrauterine insemination, preferably when the woman is in our SOURCE program (see story, p. 2) so that insemination can be timed to match ovulation," Muller noted. "Our preliminary data indicate that we are able to produce high pregnancy rates with this approach."

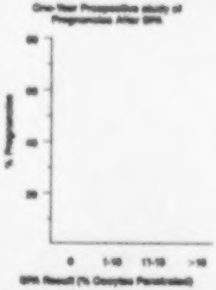


Fig. 1. Cumulative pregnancies one year after SPA in couples who had experienced at least a year of infertility and in which the female partner had no known infertility factors or treatments.

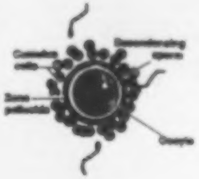


Fig. 2. Sperm capacitate and acrosome react before fusing with the oocyte.

Information on SPAs:
Charles H. Muller, Ph.D.
Director, Andrology Laboratory
(206) 543-9504

Human Embryo Cryopreservation and Donor Oocyte Programs Added to IVF Services

Couples in the UW IVF program may participate in an embryo cryopreservation program if multiple embryos are available for transfer at the end of an IVF cycle.

Transferring more than four embryos to the uterus carries a significant risk of multiple pregnancy, while not increasing the singleton pregnancy rate proportionately. Freezing extra embryos increases the couple's chance for future pregnancy without undergoing further IVF cycles.

Embryos selected for cryopreservation remain in culture for up to four days beyond the time of fresh embryo transfer. Embryos that continue to undergo cell divisions are placed in a special cryopreservative media, undergo a complex freezing process, and are stored in liquid nitrogen at − 196° C.

At present, about 50 to 70 percent of frozen embryos survive the freezing and thawing process. The current pregnancy rate for these embryos is about 8 percent per embryo. However, there is only minimal worldwide experience with human embryo cryopreservation and a definitive pregnancy rate has yet to be determined.

Extrapolating from information on other mammalian species, cryopreserved embryos can be stored up to 10 years and still be likely to develop into healthy children. There is very limited knowledge regarding the health of offspring from cryopreserved human embryos, but it appears that the spontaneous abortion rate and congenital anomaly rate are not greater than those expected for natural pregnancies.

The legal status of frozen human embryos is unknown; no legislative body in the United States has addressed this issue. In the UW program, participating couples are asked to execute both a frozen embryo consent form and separate legal statement defining the disposition of cryopreserved embryos.

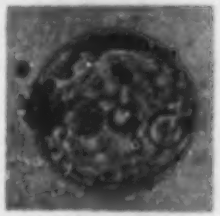
A single embryo is stored in the thin glass tube (left), then placed in a special chamber for the complex freezing process.

The frozen embryo is then inserted into a liquid nitrogen refrigerator for long-term storage at − 196° C.

In early 1988, a donor oocyte program (DOP) will become available in the IVF Program. Couples in which the woman has a healthy uterus, is less than age 40, and has experienced premature ovarian failure will be eligible.

Oocytes may be provided by a female relative or an anonymous donor (women undergoing tubal ligation who elect to donate their oocytes). The donor undergoes ovulation induction and the recipient undergoes hormone replacement therapy to synchronize the recipient's menstrual cycle to that of the donor.

The donor's oocyte are fertilized with the husband's sperm in vitro and the embryo(s) transferred two days later to the recipient's uterus. The pregnancy rate is anticipated to be 20 to 25 percent, similar to the UW IVF program pregnancy rate.



This human blastocyst at a greater than 60-cell stage is typical of the embryos selected for cryopreservation.

Information on the Embryo Cryopreservation Program:
Frank Kuzan, Ph.D.
Director, IVF Laboratory
(206) 543-0670

Information on the Donor Oocyte Program:
Michael R. Soules, M.D.
Director, Division of Reproductive Endocrinology
(206) 543-4695

Ovulation Induction Using Pergonal or GnRH Pump

For women who have chronic clomiphene citrate-resistant anovulation, ovulation induction with Pergonal or use of gonadotropin-releasing hormone (GnRH) delivered by an intermittent infusion pump offer two alternatives.

Pergonal, the trade name of a drug made from human menopausal gonadotropin (HMG), is recommended for women who have either failed to ovulate or failed to get pregnant with the use of simpler ovulation induction methods.

From 10 to 100 ampules ($25–$30 per ampule) may be used in a Pergonal cycle, depending on each woman's individual response to the drug. It is given by daily intramuscular injection until blood estradiol levels reach the 300–400 pg/ml range. The woman then begins daily ultrasound scans to monitor ovarian follicle growth.

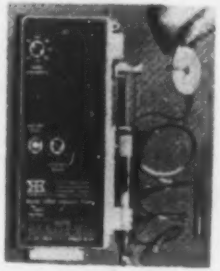
When ultrasound indicates that the ovaries are ready for ovulation, an injection of human chorionic gonadotropin (HCG) is given. Ovulation occurs approximately 36 hours later.

There are several potential side effects. Direct stimulation of the ovaries is usually associated with the development of multiple follicles, which can lead to multiple gestations and/or to ovarian hyperstimulation syndrome. Twins occur as often as 25 percent, and three or more intrauterine pregnancies occur in 4 percent of women using Pergonal.

Because each woman has a unique response to Pergonal, careful monitoring is necessary for the effective and safe use of the drug.

GnRH Pumps A Recent Advance

Three recent developments have set the stage for the use of GnRH as an alternative to Pergonal: (1) the invention of miniaturized delivery systems modeled on the insulin pump; (2) clinical availability of gonadotropin-releasing hormone (GnRH); and (3) the discovery that GnRH is secreted by the hypothalmus in an intermittent (pulsatile) pattern in ovulatory women.



The GnRH pump delivers a precise dose every 90 minutes for approximately two weeks.

Intermittent infusion pumps have been successfully used for about four years to induce ovulation with GnRH. "Because this mimics the natural pattern of gonadotropin hormone secretion in the body, this is a more physiologic process than using Pergonal," explained Dr. Michael Soules, director of the division of reproductive endocrinology. "Only one follicle develops, so the risk of hyperstimulation and multiple pregnancy is substantially reduced."

The intravenous route, in which the GnRH is delivered every 90 minutes via an intracath in the patient's forearm, is quicker and more predictable in terms of ovulation and pregnancy rates than subcutaneous GnRH therapy. The pump is worn for approximately two weeks.

"We use both Pergonal and the GnRH pump in our program," Soules said, "taking into account each patient's specific physiologic needs and her preference for one method of administration over the other."

Information on Pergonal cycles and the GnRH pump:
Michael R. Soules, M.D.
Director, Division of Reproductive Endocrinology
(206) 543–4693

Mind-Body Link Emphasized at New Reproductive and Sexual Medicine Clinic

"We believe that a healthy reproductive and sexual life involves both mind and body. When problems develop, good care includes consideration of physical, psychological, and social factors," said Dr. Richard Berger.

Berger and Dr. Julia Heiman, a clinical psychologist, direct the Reproductive and Sexual Medicine Clinic, which provides comprehensive care for male infertility and impotence, and treats other sexual problems in both men and women.

Opened this year in a medical office building in downtown Seattle, the Reproductive and Sexual Medicine Clinic is jointly operated by Harborview Medical Center and the University of Washington School of Medicine (Departments of Urology and of Psychiatry and Behavioral Sciences).

Many Reasons for Male Infertility

Common causes of male infertility are sperm allergy, a previous vasectomy, varicose veins of the scrotum, low sperm count, pituitary or other hormonal imbalance, impotence, inflammation of the genital tract, or obstruction as a result of prior infection or trauma.

Couples are routinely tested for sperm autoimmunity at the Reproductive and Sexual Medicine Clinic. Either partner may be allergic to the husband's sperm, which may make it difficult for the sperm to penetrate the cervical mucus or zona pellucida. High-dose corticosteroids help in some cases, or IVF may be an option, depending on the type of antibodies produced.

New microsurgery techniques are improving the pregnancy rate following vasovasostomy, currently about 60–70 percent. Berger is doing clinical research using tiny handmade plastic stents to help connect the ends of the cut vas. Varioceles, which occur in as many as 30 percent of all men, may also cause suboptimal fertility. Surgery or balloon occlusion of the spermatic vein can help.

If the sperm count is low, the patient's levels of LH, FSH, and testosterone are tested. Elevated FSH indicates primary testicular problems and there is little that can be done. Hormone therapy may help when hormones governed by the pituitary are the cause.

Lifestyle may also have a significant effect on sperm count. Drinking more than six ounces of alcohol a week can cause an increased number of white blood cells in the semen, and adversely influence sperm count and motility. Cigarette or marijuana smoking also has a deleterious effect on male fertility.

Penile prostheses may help men who are fertile but impotent, as may injections into the penis of papaverine and phentolamine or prostaglandin E-1. Patients can be taught to inject themselves at home to cause erection.

Body-Mind Connection

"Although medical technology and research can bring new hope to childless couples, the tests are often physically and psychologically invasive, infringing on one of the most private aspects of a couple's relationship," noted Heiman. "Given this mechanization of procreative sex, it's natural for the couple to find it easier to talk about the next procedure than their emotional reactions."

For some couples, this is manageable. For others, especially if they have been trying several years for pregnancy, or if one partner feels desperate, or if they feel there are no alternatives left, Heiman observed, "the pressure and distress become palpable. The man or woman may be very miserable and constantly edgy, and their partner may become the most convenient target for the negative feelings. This can happen without either partner realizing it and in spite of the best of intentions.

"Recent studies have found that the marital relationship is more likely to be distressed if the husband, vs. the wife, is the person identified as infertile, primarily because of the wife's anger about it."

There are two major situations in which couples with fertility problems can benefit from brief psychotherapy or counseling (one to three sessions). A key time is during the fertility work-up in order to reduce the conflict or distress involved. Since psychological stress is related to physiological regulation, a reduction of distress may facilitate conception for some couples.

Short-term counseling may help many couples deal with the physical and psychological stress of infertility treatment.

Microscopic examination of fresh semen can reveal problems with sperm count, morphology, and motility.

A few studies have shown that brief psychological intervention can help some couples conceive, especially in cases where no physical causes of infertility can be clearly identified. Why this works and for whom it seems to be most useful is an area Heiman and the clinic's postdoctoral fellow, Dr. Virginia Grafton, are beginning to study further.

Therapy can also be useful after the medical evaluation, if it becomes clear that conception is not possible. "This is difficult news for couples," said Heiman, "and it can be an important period of personal and relationship redefinition. Some people need to go through a type of grieving process before they can accept the closing of one chapter in their lives and then move into a new one that has meaning for them."

Information on the Reproductive and Sexual Medicine Clinic:
Richard E. Berger, M.D.
Julia R. Heiman, Ph.D.
Directors
(206) 223–3121

An In Vitro Fertilization Program Using Satellite Physicians

P. W. ZARUTSKIE, MD, F. B. KUZAN, PhD, D. E. MOORE, MD, M. R. SOULES, MD, AND THE UNIVERSITY OF WASHINGTON SATELLITE PHYSICIANS

In order to provide an in vitro fertilization (IVF) service for a large geographic region, we developed the concept of Satellite IVF Centers. The goals of this program were as follows: 1) to facilitate patient participation by decreasing travel expenditures, time for screening appointments, and IVF cycle cancellations, and 2) to involve community physicians in a regionalized program. We established centers in nine cities within the Washington, Alaska, Montana, and Idaho region serviced by the University of Washington, and in Alberta, Canada. A 2-day training session was held to provide participating physicians with a basic knowledge of IVF. We considered the roles of the satellite IVF physician to include identification of couples for IVF, initiation of ovulation induction cycles, and determination of appropriate induction cycles for oocyte recovery. The staff of the University Department of Laboratory Medicine standardized the methodologies for estradiol measurements and maintained a quality control analysis for all participating community laboratories. Satellite activity was coordinated through the IVF office at the University, which monitored physicians' decisions based on hormone and ultrasound data from days 7 and 8 of the stimulation cycle. Patients meeting specific ovarian response criteria arrived at the University on day 9 of the stimulation cycle and completed IVF. During 18 months, 72 patients were screened and initiated cycles at the nine participating centers. Forty-four of these patients were sent to the University for oocyte recovery, which resulted in 39 embryo transfers and eight pregnancies. This service has reached a large geographic community, dramatically reduced the cost of IVF for this community, and met with both patient and physician acceptance. *(Obstet Gynecol 72:929, 1988)*

In vitro fertilization (IVF) has become an integral part of clinical practice in reproductive medicine. Improved techniques in ovulation induction, oocyte recovery, and gamete handling have allowed some IVF programs to achieve pregnancy rates equivalent to normal fertile human reproduction.[1–3] A consensus has developed among established IVF programs that a minimum program activity of approximately 100 IVF cycles per year provides the critical patient volume necessary to maintain efficiency and economic viability. Since 1960, the University of Washington Medical Center has served as the referral and educational center for a large geographic region, including the states of Washington, Alaska, Montana, and Idaho. This referral system is known by the acronym WAMI, formed from the first initial of each of the states involved. The WAMI region represents 24% of the United States land mass but just 3% of its population. Except for Seattle, no one state or city has a population large enough to support an IVF program. Considering these conditions, patients traveled great distances to the University medical center for IVF services that often necessitated a 10–14-day stay. Therefore, we designed an IVF referral system to involve community physicians in this specialized program. The goal was to decrease patients' expenditure of time and money and thereby make IVF more generally available in the region. Named the Satellite IVF Program, the system is not a formal part of WAMI but was based on the WAMI referral and consulting system.

This report presents the initial 18-month experience with the Satellite IVF Program (June 1986 to December 1987). It provides information that other IVF programs may use to increase the volume of patients and to expand services in communities where geographic or financial conditions have resulted in limited IVF availability.

From the Department of Obstetrics and Gynecology, University of Washington, Seattle, Washington.

Co-investigators and institutions participating in the Satellite In Vitro Fertilization Program are: R. Gills, H. Hanson, R. Thompson (Anchorage, Alaska); P. Townes (Bozeman, Montana); J. Brown, T. Campbell (Missoula, Montana); P. Morell (Kalispell, Montana); T. Kent, D. Molloy (Billings, Montana); D. Barton, P. Livers, G. Poole (Boise, Idaho); S. Brisbois, H. Irwin (Spokane, Washington); P. Henderson III (Longview, Washington); and I. Tartaryn (Edmonton, Alberta, Canada).

0029-7844/88/$3.50

Materials and Methods

After examining the pattern of patient referrals to the Department of Obstetrics and Gynecology from the WAMI region, we selected nine cities in the region as potential satellite centers (Figure 1). These sites were selected on the basis of population, central location for specific geographic regions, and the presence of qualified obstetrician-gynecologists. Attractive qualifications for satellite physicians included experience in the care of infertility patients, well-established practices, and the ability to attract referrals from the community. Eighteen physicians in these nine satellite cities were contacted; 16 expressed interest in a satellite IVF program and thought they had sufficient patient volume to warrant participation in the program.

Satellite physicians contacted medical laboratories within their area to ascertain whether results of estradiol (E2) measurement could be obtained daily. Medical laboratories that expressed interest in providing this service contacted the Director of Laboratory Medicine at the University of Washington, who outlined the requirements of participation in the Satellite IVF Program. The satellite laboratories were then given specific guidelines for E2 radioimmunoassay (RIA) methodologies, including appropriate control criteria. A standard RIA kit for E2 (Serono Laboratories, Randolph, MA) was selected and used at all centers, including the University laboratory. Quality control was maintained by periodically sending patient samples from each satellite center for measurement at the University laboratory, and standard E2 samples from the University laboratory as unknowns to be assayed by the satellite centers. These results were reviewed by the University laboratory, and adjustments and corrections were made when necessary.

A 2-day training session was held at the University of Washington to acquaint the participating obstetrician-gynecologists with the basic aspects of IVF. A detailed training manual was provided during the session, outlining patient screening requirements, ultrasound and laboratory requirements, business and financial aspects, and the psychological aspects involved in managing these patients. We also provided specific directions to coordinate patient participation between the satellite center and the University. At the end of this training session, the satellite physicians were expected to make initial contact with interested patients, provide screening IVF appointments, and initiate stimulation cycles. The anticipated pattern of patient participation in the satellite program was reviewed with each satellite physician. The participating physician's office provided information brochures and applications, responded to patient inquiries, and set up screening appointments.

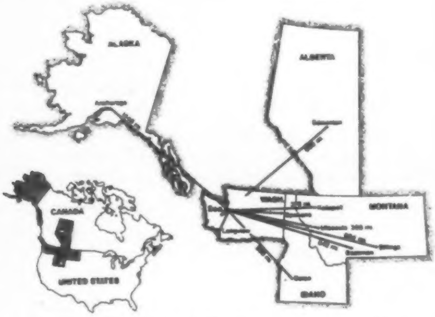


Figure 1. University of Washington satellite IVF centers.

Table 1. University of Washington Satellite In Vitro Fertilization Patient Selection Criteria

- Tubal disease
  - Irreparable damage
  - >2 yr post-reparative procedure
- Endometriosis
  - >2 yr post-medical/surgical management
- Ovulatory factor
  - Normal ovulation
  - Failed corpus luteal dysfunction therapy
- Cervical factor
  - Failed >6 mo intrauterine inseminations
- Unexplained infertility
  - Failed >12 mo empirical therapies

At the screening appointment, specific attention was given to selection criteria and the completeness of the previous infertility evaluation before acceptance into the IVF Program. Patients had to be under age 40 and meet the applicable criteria outlined in Table 1. Couples with male factor infertility or multiple infertility factors were directed to the University because these patients were not considered suitable for treatment at the satellite centers. At the screening appointment, each satellite physician gave suitable patients a satellite screening information packet developed at the central facility.

Figure 2 outlines the procedure followed for coordinating satellite IVF patients with the University center. At the completion of a screening IVF visit, if the couple qualified for the program, the satellite physician sent an acceptance packet (medical questionnaire, signed consent forms, satellite history, physical and laparoscopic forms, and the screening semen analysis) to the University IVF office. Upon receipt and review of the acceptance packet, the University program sent confir-

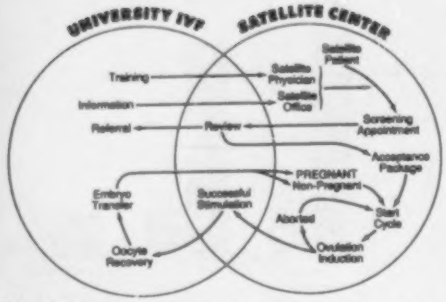

UNIVERSITY IVF
SATELLITE CENTER
Training
Information
Referral
Review
Satellite Patient
Satellite Physician
Satellite Office
Screening Appointment
Acceptance Package
PREGNANT
Non-Pregnant
Start Cycle
Aborted
Ovulation Induction
Successful Stimulation
Embryo Transfer
Oocyte Recovery

Figure 2. Integration of the satellite center with the University In Vitro Fertilization (IVF) Program.

mation to the satellite physician, with a financial agreement and clinical information packet sent to the couple.

In vitro fertilization cycle initiation and ovulation induction schedules conformed to the clinical criteria used for the central IVF program.[4] The satellite physicians were instructed to use a single ovulation induction protocol, a clomiphene citrate/human menopausal gonadotropin combination. All patients initiated treatment on cycle day 3 after informing the satellite physician and the University IVF office of menstrual onset. The ovulation induction cycles were monitored at the satellite centers, and decisions were made locally based on an algorithm (Figure 3). Because the majority of IVF patients at the University demonstrated evidence of an adequate E2 response by cycle day 8, this became the decision day for the satellite patients. From our published data,[4] most IVF pregnancies are achieved when the day 8 E2 values are above 450 pg/mL. Therefore, this established E2 level became the criterion for continuation in the satellite program so that patients could travel to the central facility between cycle days 8 and 9 to complete follicular monitoring, hCG administration, oocyte recovery, and embryo transfer. Satellite physicians were able to consult with the University IVF physician 24 hours a day, 7 days a week. Because satellite centers were located in three time zones, specific time requirements were established for office-to-office communications.

After embryo transfer, patients returned to the satellite program for a serum pregnancy test 14 days after oocyte recovery. Empirical progesterone supplementa-

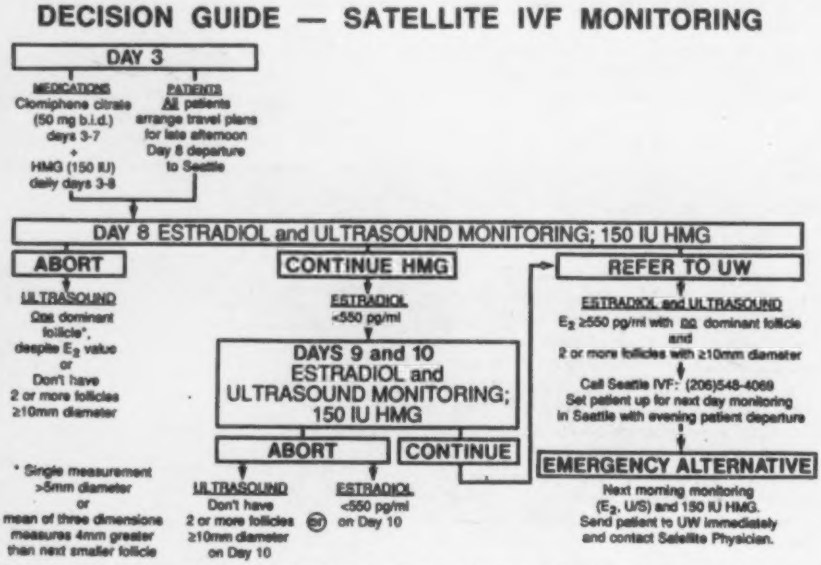

DECISION GUIDE — SATELLITE IVF MONITORING
DAY 3
MEDICATIONS
Clomiphene citrate (50 mg b.i.d.) days 3-7 + HMG (150 IU) daily days 3-8
PATIENTS
All patients arrange travel plans for late afternoon Day 8 departure to Seattle
DAY 8 ESTRADIOL and ULTRASOUND MONITORING; 150 IU HMG
ABORT
ULTRASOUND
One dominant follicle*, despite E_2 value or Don't have 2 or more follicles ≥10mm diameter
* Single measurement >5mm diameter or mean of three dimensions measures 4mm greater than next smaller follicle
CONTINUE HMG
ESTRADIOL <550 pg/ml
DAYS 9 and 10 ESTRADIOL and ULTRASOUND MONITORING; 150 IU HMG
ABORT
ULTRASOUND
Don't have 2 or more follicles ≥10mm diameter on Day 10
or
ESTRADIOL
<550 pg/ml on Day 10
CONTINUE
REFER TO UW
ESTRADIOL and ULTRASOUND
E_2 ≥550 pg/ml with no dominant follicle and 2 or more follicles with ≥10mm diameter
Call Seattle IVF: (206)548-4069
Set patient up for next day monitoring in Seattle with evening patient departure
EMERGENCY ALTERNATIVE
Next morning monitoring (E_2, U/S) and 150 IU HMG. Send patient to UW immediately and contact Satellite Physician.

Figure 3. Ovulation induction algorithm for the satellite In Vitro Fertilization (IVF) Centers. HMG = human menopausal gonadotropin; E_2 = estradiol; UW = University of Washington; U/S = ultrasound.

Table 2. Satellite In Vitro Fertilization Program, University of Washington: June 1986 to December 1987

	Satellite	U of WA only	Total program
Cycles initiated	72 (29%)*	175 (71%)*	247
Patients referred to Seattle	44	NA	
Oocyte recoveries	41 (57%)†‡	137 (78%)†‡	178 (72%)†
Embryo transfers	39 (95%)§	130 (95%)§	169 (95%)§
Clinical pregnancies‖	8 (11%)†	28 (16%)†	36 (15%)†
	(20%)§	(20%)§	(20%)§

U of WA = University of Washington; NA = not applicable.

[*] Percentage of total program.

[†] Percentage of cycles initiated.

[‡] $P < .005$.

[§] Percentage of patients who had oocytes recovered.

[‖] Fetal viability demonstrated by sonography.

tion was used after embryo transfer (progesterone in oil, 25 mg intramuscularly daily). Pregnancies were reported only after sonographic confirmation of fetal viability. We used a computer program to provide a cycle summary, store and retrieve data for research, and provide follow-up correspondence for referring physicians and patients. We chose RBase System 5 as the data base system because of its relational capabilities and its flexibility for the addition of parameters in the future. ReflexR was used to access this data for graphing.

We collected data regarding all aspects of the Satellite IVF Program for the first 18 months of operation (Table 2). Cycle parameters and cycle outcome results were analyzed by paired and unpaired t test statistics and χ^2 test for two independent samples when appropriate.

Results

Satellite IVF Program patients differed significantly from University patients with respect to the proportion who went to oocyte recovery after initiation of a cycle (78% for the University patients versus 57% for the satellite patients; $P < .005$). In other words, the cycle cancellation rate was higher in the satellite clinics. Because a higher percentage of satellite cycles was canceled, the satellite pregnancy rate per cycle was less than that of the University-based program (11 versus 16%; not significantly different). However, once the patient had been referred for oocyte recovery, there were no differences in the percentage of patients who proceeded to embryo transfer (95% in each) and the clinical pregnancy rate per oocyte recovery (20% in each). There were no differences between the satellite and University IVF patients with respect to the primary infertility diagnosis, eg, irreparable tubal disease; parameters of ovulation induction such as peak E2 level; number of oocytes recovered; or the number of embryos available for transfer.

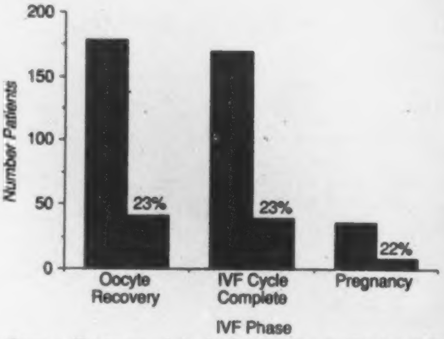


Figure 4. The impact of the Satellite In Vitro Fertilization (IVF) Program on patient volume at the University Center. Study period was from June 1986 to December 1987. Dark bars = total University of Washington IVF Program; light bars = Satellite Program.

Three patients referred to Seattle for oocyte recovery received alternative therapy. All had fewer than three follicles meeting the induction criteria and had at least one patent fallopian tube. Therefore, each received a timed intrauterine insemination. No pregnancies resulted in these patients.

Figure 4 shows the impact of the Satellite IVF Program on the total patient volume at the University Hospital. Satellite centers provided 23% of the patient volume for oocyte recovery, 23% of the cycles completed, and 22% of the total pregnancies.

In Table 3, expenses incurred by a hypothetical patient from the satellite region who would have had a

Table 3. Financial Impact of Satellite In Vitro Fertilization Program (Estimate for First 18 Months)

Screening appointment ($ saved) (N = 72)		
Average cost of flight for couple	800	
Hotel accommodations (2 d)	140	
Per diem expenses (2 d)	110	
Subtotal	1,050	
Total		75,600
Canceled cycle ($ saved) (N = 28)		
Average cost of flight for couple	800	
Hotel accommodations (7 d)	490	
Per diem expenses (7 d)	700	
Subtotal	1,990	
Total	3,040	55,720
Grand total savings		131,320

screening appointment and cycle initiation at the University are contrasted with typical expenses from the satellite program. Before the satellite program, if an IVF cycle was canceled because of poor ovulation induction, the patient would have incurred costs for traveling to and from Seattle both for the screening appointment and for the canceled cycle. Satellite patients ($N = 72$) who avoided a screening appointment at the University saved an estimated total of $75,600. An additional estimated savings of $55,720 accrued to satellite patients ($N = 28$) whose cycles were canceled and who therefore did not travel to the University Program. Thus, this group of 72 satellite patients had an estimated net savings of $131,320.

Discussion

The recent development of IVF as an effective treatment of end-stage infertility has created an increasing worldwide demand for this reproductive technology. Because of the complexity and intensity of IVF, a detailed administrative component is necessary to support these specialized treatment programs. From the clinical perspective, the organization and administration of an IVF program requires the following: 1) a well-structured and specialized program within the larger framework of reproductive endocrinology services, 2) adherence to mandatory strict quality control measures at all levels to assure the best possible results, 3) availability of a specially designed computer program to store and retrieve information, 4) effective initial screening of candidates, 5) patient information and education, 6) ability to monitor patient flow during active cycles, 7) coordination of the various components of the IVF program (eg, physicians, nurses, laboratory, etc), and 8) a balance between new and repeat patient entry into the program. This organization and structure has been outlined[5] for the first IVF program in the United States.

Once our IVF program was established with an acceptable pregnancy rate, the need for satellite IVF centers became apparent because of the relatively large geographical referral area. To achieve the specific goals outlined for the Satellite IVF program, the organization of our IVF Program was modified to allow for a high standard of patient care even though the program became decentralized because of expanded regional participation.

To reach these goals, we defined the role of the satellite IVF physician as screening couples and initiating cycles. Satellite physicians were able to screen patients with a high rate of acceptance into the University program. After the patients were screened and accepted into the satellite program, the satellite physicians could initiate an ovulation induction cycle with approval given by the central University IVF office. Most IVF programs have demonstrated that careful ovulation induction monitoring is necessary to achieve successful oocyte fertilization and pregnancies. This report has shown that with an educational program for regional physicians incorporating adequate support training in ultrasonography and E2 testing, the satellite centers were able to successfully fulfill expectations in terms of cycle initiation and monitoring. Following the criteria set for E2 levels and follicle number on day 8, more satellite cycles were canceled than University cycles. Based on the total number of cycles, the satellite centers achieved a lower pregnancy rate than the University (11 versus 16%). However, the strict criteria used at the satellite centers were confirmed to be effective, because pregnancy rates from University and satellite program patients were similar after oocyte recovery (20%) and embryo replacement (21%).

Cost savings to the patients were substantial. By having the initial screening appointment locally, the couple saved the expense of a trip to Seattle. Those whose ovulation induction was canceled experienced an additional savings. Although it cannot be quantitated, the employed patient had an additional savings because she did not have to be absent from work for these times. The dollar savings combined with the convenience may allow patients to participate in additional cycles, thereby optimizing their chances for an oocyte recovery and pregnancy.

Overall, a significant proportion of the total University program activity came from the satellite component (Figure 4). These results indicate that incorporating community physicians in the activities of the University program did not compromise the overall outcome of this high-technology procedure.

The main problem experienced with the satellite program was maintenance of clear lines of communication between the University program and the satellite centers. A computer program was designed to facilitate this communication and to meet the needs of both the satellite program and the University program. The computer program can record both completed and active cycle files, permitting follow-up information on patients to be relayed to the satellite physician. Follow-up information on pregnancies is also recorded in the computer program.

The Satellite IVF Program has also expanded community involvement in other areas of reproductive endocrinology and infertility. Some satellite centers have established 1) improved controlled ovulation induction monitoring programs for their local patients, 2) improved evaluation of male fertility, and 3) the new therapeutic modality using intensive ovulation induction and intrauterine insemination.

Future directions for the satellite program include establishing additional centers and expanding the scope of the program to include participation in alternative IVF programs such as a donor oocyte program and more complex factor infertility treatments.

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RECEIVED
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Hon. Ron Wyden

IVF/GIFT SURVEY

CLINIC NAME: Rice & Associates
ADDRESS: Fifth & Browne Med. Center West
Suite #410
Spokane, WA 99203

CONTACT PERSON: George H. Rice, M.D.
PHONE NUMBER: (509) 455-8111

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/1/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ________
   - (c) University based ________
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 1

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 1

6. How many other professionals participate in your clinic?
   - (a) Physicians 2
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists -
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 2
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 2
   - (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? 6 mths.

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF Feb. 1988 GIFT Sept. 1988

9. How many different patients were stimulated?
1987 IVF _0_ 1988 IVF _1_
GIFT _0_ GIFT _2_

10. How many stimulation cycles were performed?
1987 IVF _0_ 1988 IVF _1_
GIFT _0_ GIFT _2_

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 _0_ 1988 _3_

How many embryo transfer cycles were performed?
1987 _0_ 1988 _1_

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 _0_ 1988 _2_

13. What were the number and percentage of patients on IRB approved research protocols?
1987 _0_ _-_% 1988 _3_ _100_%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF _0_ ___% 1988 IVF ___ ___%
GIFT _0_ ___% GIFT ___ ___%
(b) Endometriosis:
1987 IVF _0 =_ ___% 1988 IVF ___ ___%
GIFT _0_ ___% GIFT ___ ___%
(c) Male infertility:
1987 IVF _0_ ___% 1988 IVF ___ ___%
GIFT _0_ ___% GIFT ___ ___%
(d) Unexplained infertility:
1987 IVF _0_ ___% 1988 IVF ___ ___%
GIFT _0_ ___% GIFT ___ ___%
(e) Other (explain): ______________________
1987 IVF _0_ ___% 1988 IVF ___ ___%
GIFT _0_ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF _0_ ___% 1988 IVF _0_ ___%
GIFT _0_ ___% GIFT _0_ ___%
(b) 31-35:
1987 IVF _0_ ___% 1988 IVF _0_ ___%
GIFT _0_ ___% GIFT _0_ ___%
(c) 36-40:
1987 IVF _0_ ___% 1988 IVF _0_ ___%
GIFT _0_ ___% GIFT _0_ ___%

(d) 41-45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

(e) >45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 2

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 - % ______
GIFT 0 - % ______

1988 IVF 0 - % ______
GIFT 2 100 % each with twin pregnancies

21. What are the qualifications of the director of the embryo laboratory? Ph.D 1975 U.C.-Davis-Professor of Physiology Washington State University, 13 yrs. laboratory experiences.

22. Who supervises the laboratory director? G.H. Rice, MD.

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
______

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists ______
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

IVF/GIFT SURVEY

CLINIC NAME: Fertility Clinic of Puget Sound
ADDRESS: So. 36th and Pacific Avenue
Tacoma, Washington 98304

CONTACT PERSON: Dianne Smith
PHONE NUMBER: (206) 475-5433

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 10/31/88

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based X
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? None

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians 2 (as in Question 5)
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 6
   - (d) Embryo Lab Technicians/Technologists 1
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 5
   - (i) Other (specify) Andrologists 1

7. How many years has your infertility clinic been in operation? 10

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1985 GIFT 1985

9. How many different patients were stimulated?
1987 IVF 35 1988 IVF 16
GIFT 72 GIFT 26

10. How many stimulation cycles were performed?
1987 IVF 45 1988 IVF 17
GIFT 111 GIFT 26

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 39 1988 17

How many embryo transfer cycles were performed?
1987 39 1988 16

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 103 1988 26

13. What were the number and percentage of patients on IRB approved research protocols?
1987 * ___% 1988 * ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF 10 60%
GIFT ___ ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF 2 12 %
GIFT ___ ___% GIFT 15 58 %
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF 0 ___%
GIFT ___ ___% GIFT 9 35 %
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF 0 ___%
GIFT ___ ___% GIFT 2 8 %
(e) Other (explain): ___
1987 IVF ___ ___% 1988 IVF 5 29 %
GIFT ___ ___% GIFT 0 ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF 3 17 %
GIFT ___ ___% GIFT 3 11 %
(b) 31-35:
1987 IVF ___ ___% 1988 IVF 6 35 %
GIFT ___ ___% GIFT 12 46 %
(c) 36-40:
1987 IVF ___ ___% 1988 IVF 10 59 %
GIFT ___ ___% GIFT 9 35 %

*Any research protocols are approved by an institutional review board.

(d) 41-45:
1987 IVF ___ ___% 1988 IVF 0 ___%
GIFT ___ ___% GIFT 0 ___%
(e) >45:
1987 IVF ___ ___% 1988 IVF 0 ___%
GIFT ___ ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF 4 1988 IVF 1 - 6%
GIFT 35 GIFT 8 - 31%
Counted as clinical pregnancy only when gestational sac observed.
17. How many women delivered live infants from IVF/GIFT?
1987 IVF 4 1988 IVF Most not yet delivered
GIFT ___ GIFT Most not yet delivered
Data from year of conception.
18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF All delivered 1988 IVF 1 - 6%
GIFT All delivered GIFT 8 - 31%

19. How many ectopic pregnancies resulted?
1987 IVF 4 1988 IVF 0
GIFT 2 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 4 11 % No multiples
GIFT 28 25 % 2 sets twins, 1 set triplets.
4 additional patients lost to follow-up but completed first trimester.
1988 IVF ___ ___% Number not yet available.
GIFT ___ ___% Births will occur in 1989 for most patients.
*Data from year of conception, not year of birth.
21. What are the qualifications of the director of the embryo laboratory? Formerly Research Scientist II at University of Washington. 15 years animal and human experience in IVF and preimplantation embryo. Previously established two other IVF laboratories for successful programs.
22. Who supervises the laboratory director? ___
Physician Program Director
23. Does the clinic participate in an external laboratory proficiency testing program? Yes
If the answer is yes, please specify which program.
Reference laboratory cross-testing for RIA's at Swedish Hospital Lab. Mouse system testing at Univ. of Washington, Seattle.
24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? Yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians 0
    (b) Laboratory scientists (PhDs) 0
    (c) Embryo laboratory technicians/technologists 2
    (d) Nurses 6
    (e) Other (explain) 0

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

The two physicians who direct this fertility clinic have specialized in treating fertility patients for more than ten years. They have significant experience in use of fertility medications as well as in corrective surgery for fertility problems. Both have had formal training in gynecologic microsurgery and laser surgery. Both have applications pending to become members of the Society of Reproductive Surgeons of the AFS. The embryologist has more than 15 years experience with sperm, mammalian eggs and preimplantation embryos. As a smaller clinic, the physicians are able to personally review the status of all patients receiving fertility medications during any stimulation cycle.

IVF/GIFT SURVEY

CLINIC NAME: Seattle Fertility & Gynecology Clinic
ADDRESS: 1229 Madison Avenue, Suite 1220
Seattle, Washington 98104

CONTACT PERSON: Robert E. McIntosh, M.D.
PHONE NUMBER: 206/682-9935

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 9/30/88

2. Does your clinic perform IVF/GIFT treatments? yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private X
   - (b) Community hospital based ____
   - (c) University based ____
   - (d) Other (explain) ____

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? none

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2

6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 6
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 3
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 0
   - (i) Other (specify) 0

7. How many years has your infertility clinic been in operation? 38 years

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF January 1984 GIFT August 1985

9. How many different patients were stimulated?
1987 IVF 68 1988 IVF 109
GIFT 109 GIFT 54

10. How many stimulation cycles were performed?
1987 IVF 81 1988 IVF 120
GIFT 141 GIFT 57

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 64 1988 98

How many embryo transfer cycles were performed?
1987 54 1988 84

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 96 1988 47

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 % 1988 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 43 86 % 1988 IVF 54 66 %
GIFT 12 15 % GIFT 7 15 %
(b) Endometriosis:
1987 IVF 3 6 % 1988 IVF 14 17 %
GIFT 30 37 % GIFT 15 32 %
(c) Male infertility:
1987 IVF 2 4 % 1988 IVF 5 6 %
GIFT 27 34 % GIFT 13 28 %
(d) Unexplained infertility:
1987 IVF 1 2 % 1988 IVF 7 8 %
GIFT 2 2 % GIFT 8 17 %
(e) Other (explain): ovulation dysfunction
1987 IVF 1 2 % 1988 IVF 1 1 %
GIFT 8 10 % GIFT 4 9 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 12 17 % 1988 IVF 20 19 %
GIFT 25 23 % GIFT 11 20 %
(b) 31-35:
1987 IVF 29 41 % 1988 IVF 43 40 %
GIFT 40 37 % GIFT 22 41 %
(c) 36-40:
1987 IVF 24 34 % 1988 IVF 32 30 %
GIFT 37 34 % GIFT 15 28 %

(d) 41-45:
1987 IVF 5 7 % 1988 IVF 11 10 %
GIFT 7 6 % GIFT 5 9 %
(e) >45:
1987 IVF 0 0 % 1988 IVF 2 2 %
GIFT 0 0 % GIFT 1 2 %

16. How many clinical pregnancies were produced?
1987 IVF 8 1988 IVF 19
GIFT 18 GIFT 17

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 8 1988 IVF 7
GIFT 27 GIFT 10

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 12
GIFT 0 GIFT 11

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 1
GIFT 1 GIFT 1

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 2 ___ % one twin, one triplet
GIFT 7 ___ % twins

1988 IVF 3 ___ % two twins, one quadruplet
GIFT 3 ___ % twins

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Reproductive Physiology with research experience ni estradiol mechanism of action and animal IVF.

22. Who supervises the laboratory director? Laurence E. Karp, M.D.

23. Does the clinic participate in an external laboratory proficiency testing program? no
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (*Fertility and Sterility*, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? ___no___

27. Does the clinic train individuals in IVF or GIFT? ___upon request___ If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ___8___
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses ___6___
    (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Reproductive Genetics Laboratory (IVF/GIFT survey enclosed) serves as the IVF laboratory for several private physicians. All procedures are performed according to common protocols. Doctors McIntosh and Stewart are reporting their results separately from the combined results of the Reproductive Genetics Laboratory.

Seattle Women's Clinic
P. + LBD

RECEIVED
JAN 9 1989
Hon. Ron Wyden

IVF/GIFT SURVEY

CLINIC NAME: Seattle Womens Clinic
ADDRESS: 501 Broadway
Seattle 98112
Suite 511

CONTACT PERSON: Mary Robert RN nurse coordinator
PHONE NUMBER: 1-206-312-2200

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? /

2. Does your clinic perform IVF/GIFT treatments? ______
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based [✓]
   - (c) University based ______
   - (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? ______

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 5

6. How many other professionals participate in your clinic?
   - (a) Physicians 2
   - (b) Laboratory Scientists (PhDs) 2
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists 2
   - (f) Radiology (Ultrasound) Technicians 1
   - (g) Psychologists/Counselors 1
   - (h) Secretaries 1
   - (i) Other (specify) ______

7. How many years has your infertility clinic been in operation? 24 months

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 5/87 GIFT 1/87

9. How many different patients were stimulated?
1987 IVF 4 1988 IVF 1
GIFT 6 GIFT 15

10. How many stimulation cycles were performed?
1987 IVF 4 1988 IVF 1
GIFT 6 GIFT 6

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 3 1988 1

How many embryo transfer cycles were performed?
1987 3 1988 1

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 4 1988 4

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:

different patient treated

(a) Tubal factor:
1987 IVF 3 ___% 1988 IVF 1 ___%
GIFT 0 ___% GIFT 0 ___%
(b) Endometriosis:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 1 ___% GIFT 0 ___%
(c) Male infertility:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 2 ___% GIFT 3 ___%
(d) Unexplained infertility:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 1 ___%
(e) Other (explain): ovulation dysfunction
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 1 ___% GIFT 0 ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 0 ___% 1988 IVF 1 ___%
GIFT 2 ___% GIFT 2 ___%
(b) 31-35:
1987 IVF 2 ___% 1988 IVF 0 ___%
GIFT 1 ___% GIFT 2 ___%
(c) 36-40:
1987 IVF 1 ___% 1988 IVF 0 ___%
GIFT 1 ___% GIFT 0 ___%

(d) 41-45:
1987 IVF 1 ___% 1988 IVF 0 ___%
GIFT 1 ___% GIFT 1 ___%

(e) >45:
1987 IVF 0 ___% 1988 IVF 0 ___%
GIFT 0 ___% GIFT 0 ___%

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 0
GIFT 2 GIFT 1

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 1 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 0
GIFT 0 GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 0 ___% ______________________
GIFT 0 ___% ______________________

1988 IVF 0 ___% ______________________
GIFT 0 ___% ______________________

21. What are the qualifications of the director of the embryo laboratory? PhD in Reproductive Physiology with experience in steroid hormones and animal IVF

22. Who supervises the laboratory director? Laurence E Karp

23. Does the clinic participate in an external laboratory proficiency testing program? no.
If the answer is yes, please specify which program.
____

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? no

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? no

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) 1
    (c) Embryo laboratory technicians/technologists 1
    (d) Nurses ________
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions ,to more fully explain the operation of your clinic.

Sent 2/13/89

IVF/GIFT SURVEY

CLINIC NAME: West Virginia University
ADDRESS: Department of Ob/Gyn
830 Pennsylvania Avenue
Suite 304
Charleston, WV 25302
CONTACT PERSON: Sherif G. Awadalla, M.D.
PHONE NUMBER: (304) 342-0816

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 12/88

2. Does your clinic perform IVF/GIFT treatments? YES
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ________
   - (b) Community hospital based ________
   - (c) University based X
   - (d) Other (explain) ________

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? one

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? one

6. How many other professionals participate in your clinic?
   - (a) Physicians ________
   - (b) Laboratory Scientists (PhDs) ________
   - (c) Nurses one R.N.
   - (d) Embryo Lab Technicians/Technologists two
   - (e) Other Lab Technicians/Technologists one
   - (f) Radiology (Ultrasound) Technicians one
   - (g) Psychologists/Counselors none
   - (h) Secretaries one
   - (i) Other (specify) ________

7. How many years has your infertility clinic been in operation? one

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF January 1988 GIFT January 1988

9. How many different patients were stimulated?
1987 IVF None 1988 IVF 17
GIFT None GIFT 32

10. How many stimulation cycles were performed?
1987 IVF None 1988 IVF 28
GIFT None GIFT 30

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 None 1988 19

How many embryo transfer cycles were performed?
1987 None 1988 14

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 None 1988 35

13. What were the number and percentage of patients on IRB approved research protocols?
1987 None ___ % 1988 None %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF ___ ___% 1988 IVF ___ 50%
GIFT ___ ___% GIFT ___ 0 %
(b) Endometriosis:
1987 IVF ___ ___% 1988 IVF ___ 0 %
GIFT ___ ___% GIFT ___ 40%
(c) Male infertility:
1987 IVF ___ ___% 1988 IVF ___ 50%
GIFT ___ ___% GIFT ___ 40%
(d) Unexplained infertility:
1987 IVF ___ ___% 1988 IVF ___ 0 %
GIFT ___ ___% GIFT ___ 20%
(e) Other (explain): ______
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF ___ ___% 1988 IVF ___ 10%
GIFT ___ ___% GIFT ___ 10%
(b) 31-35:
1987 IVF ___ ___% 1988 IVF ___ 30%
GIFT ___ ___% GIFT ___ 40%
(c) 36-40:
1987 IVF ___ ___% 1988 IVF ___ 60%
GIFT ___ ___% GIFT ___ 50%

(d) 41-45:
1987 IVF ___% 1988 IVF ___%
GIFT ___% GIFT ___%

(e) >45:
1987 IVF ___% 1988 IVF ___%
GIFT ___% GIFT ___%

16. How many clinical pregnancies were produced?
1987 IVF ___ 1988 IVF 2
GIFT ___ GIFT 13

17. How many women delivered live infants from IVF/GIFT?
1987 IVF ___ 1988 IVF 0
GIFT ___ GIFT 5

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF ___ 1988 IVF 1
GIFT ___ GIFT 4

19. How many ectopic pregnancies resulted?
1987 IVF ___ 1988 IVF 1
GIFT ___ GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF ___ ___% None
GIFT ___ ___% None

1988 IVF ___ 0% ___
GIFT ___ 20% Twins

21. What are the qualifications of the director of the embryo laboratory? board eligible reproductive endocrinologist

22. Who supervises the laboratory director? Department Chairperson

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.
___

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? No

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    - (a) Physicians ______
    - (b) Laboratory scientists (PhDs) ______
    - (c) Embryo laboratory technicians/technologists ______
    - (d) Nurses ______
    - (e) Other (explain) ______

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

CHARLESTON AREA MEDICAL CENTER
WEST VIRGINIA UNIVERSITY HEALTH SCIENCES CENTER

DEPARTMENT OF OBSTETRICS AND GYNECOLOGY
Suite 304, 830 Pennsylvania Avenue
Charleston, WV 25302
Telephone (304) 342-0816

West Virginia
University

May 31, 1989

Representative Ron Wyden
2452 Rayburn Building
Washington, DC 20515

RE: Recent survey of IVF and GIFT

Dear Representative Wyden:

Recently we contributed our data for the survey relative to results of in vitro fertilization and GIFT procedure for 1987 and 1988. You were kind enough to return sheets containing information compiled nationally. I noticed that our entry as far as GIFT procedures performed for 1988 is completely inaccurate. It indicates that we did not perform any GIFT procedures during that time period. I am enclosing a copy of the original survey sheet which details that in fact we did perform 35 GIFT procedures with 13 clinical pregnancies. Given that this data has been distributed nationally, it certainly has put us in an unfavorable position. I think it would be most gracious of you to make the appropriate corrections on the data sheet and redistribute them. While I have checked our original information relative to combined GIFT and IVF and IVF separately and it appears correct, the information listing us in the 1988 GIFT table is clearly incorrect.

I am enclosing copy of our original questionnaire to aid in recompiling this information. I appreciate your help in this matter.

Sincerely,

Sherif G. Awadalla, M.D.
Assistant Professor
Department of Ob/Gyn
West Virginia University

SGA/pbp

Enclosures

Medical Education programs sponsored by the West Virginia University Health Sciences Center and the Charleston Area Medical Center.

IVF/GIFT SURVEY

CLINIC NAME: Family Fertility Program
ADDRESS: 1818 No. Meade St.
Appleton, WI, 54911

CONTACT PERSON: John S. Harris MD.
PHONE NUMBER: (414)739-0114

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the never clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? November, 1988
2. Does your clinic perform IVF/GIFT treatments? yes
   (If the answer is no, there is no need to complete the remainder of the questionnaire.)
3. What type of clinic do you operate? (Place X in appropriate space)
   - (a) Private ______
   - (b) Community hospital based ✓
   - (c) University based ______
   - (d) Other (explain) ______
4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 0
5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 2
6. How many other professionals participate in your clinic?
   - (a) Physicians 0
   - (b) Laboratory Scientists (PhDs) 1
   - (c) Nurses 2
   - (d) Embryo Lab Technicians/Technologists 2
   - (e) Other Lab Technicians/Technologists ______ }*
   - (f) Radiology (Ultrasound) Technicians ______ }*
   - (g) Psychologists/Counselors 0
   - (h) Secretaries 0
   - (i) Other (specify) ______
7. How many years has your infertility clinic been in operation? 2
8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF April, 1986 GIFT Nov., 1987

* Please see Addendum

9. How many different patients were stimulated?
1987 IVF 8 1988 IVF 8
GIFT 1 GIFT 11

10. How many stimulation cycles were performed?
1987 IVF 11 1988 IVF 8
GIFT 1 GIFT 12

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 11 1988 8

How many embryo transfer cycles were performed?
1987 7 1988 6

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 1 1988 12

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 ___% 1988 0 ___%

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 6 75% 1988 IVF 3 33% *
GIFT 0 0% GIFT 0 0%
(b) Endometriosis:
1987 IVF 1 12.5% 1988 IVF 1 12.5%
GIFT 0 0% GIFT 2 17%
(c) Male infertility:
1987 IVF 2 8% 1988 IVF 3 33%
GIFT 1 100% GIFT 3 25%
(d) Unexplained infertility:
1987 IVF 1 12.5% 1988 IVF 1 12.5%
GIFT 0 0% GIFT 5 41%
(e) Other (explain): ______________
1987 IVF ___ ___% 1988 IVF ___ ___%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 6 75% 1988 IVF 3 37.5%
GIFT 0 0% GIFT 5 43%
(b) 31-35:
1987 IVF 2 25% 1988 IVF 4 50%
GIFT 1 100% GIFT 2 17%
(c) 36-40:
1987 IVF 0 0% 1988 IVF 1 12.5%
GIFT 0 0% GIFT 4 34%

(d) 41-45:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 0 0%
(e) >45:
1987 IVF 0 0% 1988 IVF 0 0%
GIFT 0 0% GIFT 0 0%

16. How many clinical pregnancies were produced?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 6

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 1 1988 IVF 0
GIFT 0 GIFT 1

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 3

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births? *
1987 IVF 0 __%
GIFT 0 __%

1988 IVF 0 __%
GIFT 0 __%

21. What are the qualifications of the director of the embryo laboratory? *

22. Who supervises the laboratory director? Hospital V.P.; Co-director relationship with Medical Director of Fertility Program.

23. Does the clinic participate in an external laboratory proficiency testing program? yes
If the answer is yes, please specify which program.
Joint Commission on Accreditation of Hospitals

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

* Please see Addendum

26. Is the clinic a member of the Society for Assisted Reproductive Technology? No, but hope to be in just a couple months, when we will have met the criteria for application.

27. Does the clinic train individuals in IVF or GIFT? yes
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ________
    (c) Embryo laboratory technicians/technologists 4
    (d) Nurses ________
    (e) Other (explain) * 4

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Addendum

6. a,b Our hormone assays are done at Bellin Hospital, Green Bay, WI, an accredited lab. Ultrasounds for follicular studies are done by the Appleton Medical Center Radiology Dept. - also accredited.

14. In 1988, only 3 patients were treated with IVF alone. Five IVF patients were done in combination with GIFT, after transferring the maximum four oocytes to the tubes, using the oocytes exceeding those four.

20. One GIFT pregnancy was triplets, which miscarried at 8wk.
One GIFT pregnancy is twins, ongoing - due Feb. 89

21. Director of embryo labs has a PhD. Has done research and published articles on oogenesis, fertilization, embryogenesis of Elasmobranchs, Echinoderms, Amphibians and Mammals. Has received ART training at Harvard Medical School, S.E. Fertility Clinic, Johns Hopkins, Tufts, John Muir Hospital. Has attended AFS meetings in Toronto, Reno, Madison and Atlanta.

27. Four technologists have been trained by our Embryologist to work in andrology testing area, media preparation and assisting in the Embryo Lab. at the time of oocyte retrievals. Four preprofessional, premedical college undergraduates have done summer projects involving training techniques, ethical problems, research methods and data retrieval.

28. On inception of the program we limited candidacy for acceptance to married couples, with no freezing of embryos and no donors, and no surrogacy. We are now gearing up to include those who need sperm donors and possibly oocyte donors and are increasing our capabilities to do embryo freezing. Single women are still excluded.

We have participated in the AFS IVF registry since its inception.

The entire IVF-GIFT team have attended the annual AFS meetings each year and are all members of AFS. A number of regional meetings (Seattle, Madison, Washington D.C., Vancouver) covering related topics have been attended by the Scientific and Medical Directors)

We invited a consultant, Dr. Sander Shapiro, who is head of Gyn Endocrinology & Infertility at U. Wis., Madison, to critique our program, facilities and protocols, six months after we started in Nov., 1986.

IVF/GIFT SURVEY

CLINIC NAME: University of Wisconsin-Madison Infertility Clinic
ADDRESS: H4/630 CSC
600 Highland Ave.
Madison, WI 53792

CONTACT PERSON: Dr Sander Shapiro
PHONE NUMBER: 608-263-1217

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? December, 1988

2. Does your clinic perform IVF/GIFT treatments? Yes
(If the answer is no, there is no need to complete the remainder of the questionnaire.)

3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private ______
   (b) Community hospital based ______
   (c) University based X
   (d) Other (explain) ______

4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? 3

5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? 0

6. How many other professionals participate in your clinic?
   (a) Physicians 3
   (b) Laboratory Scientists (PhDs) 1
   (c) Nurses 1
   (d) Embryo Lab Technicians/Technologists 2
   (e) Other Lab Technicians/Technologists 0
   (f) Radiology (Ultrasound) Technicians 3
   (g) Psychologists/Counselors 0
   (h) Secretaries 1
   (i) Other (specify) 0

7. How many years has your infertility clinic been in operation? 5

8. When were the clinic's first IVF/GIFT stimulation cycles?
IVF 1983 GIFT 1988

9. How many different patients were stimulated?
1987 IVF 42 1988 IVF 50
GIFT 0 GIFT 1

10. How many stimulation cycles were performed?
1987 IVF 69 1988 IVF 78
GIFT 0 GIFT 1

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 31 1988 36

How many embryo transfer cycles were performed?
1987 30 1988 35

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 0 1988 1

13. What were the number and percentage of patients on IRB approved research protocols?
1987 – 0 % 1988 – 0 %

14. What were the number and percentage of patients treated for:
(a) Tubal factor:
1987 IVF 7 22.6 % 1988 IVF 6 16.7 %
GIFT – – % GIFT 0 – %
(b) Endometriosis:
1987 IVF 0 – % 1988 IVF 0 – %
GIFT – – % GIFT 0 – %
(c) Male infertility:
1987 IVF 0 – % 1988 IVF 0 – %
GIFT – – % GIFT 0 – %
(d) Unexplained infertility:
1987 IVF 0 – % 1988 IVF 0 – %
GIFT – – % GIFT 0 – %
(e) Other (explain): Each patient has 2 or more of the conditions listed above
1987 IVF 24 77.4 % 1988 IVF 30 83.3 %
GIFT – – % GIFT 1 100 %

15. What were the number and percentage of patients in the following age groups:
(a) <31:
1987 IVF 6 ___ % 1988 IVF 11 ___ %
GIFT – – % GIFT 0 – %
(b) 31-35:
1987 IVF 15 ___ % 1988 IVF 17 ___ %
GIFT – – % GIFT 1 100 %
(c) 36-40:
1987 IVF 10 ___ % 1988 IVF 8 ___ %
GIFT – – % GIFT 0 – %

(d) 41-45:
1987 IVF 0 — % 1988 IVF 0 — %
GIFT — — % GIFT 0 — %

(e) >45:
1987 IVF 0 ___ % 1988 IVF 0 — %
GIFT — — % GIFT 0 — %

16. How many clinical pregnancies were produced?
1987 IVF 4 1988 IVF 4
GIFT — GIFT 0

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 2 1988 IVF 2
GIFT — GIFT 0

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF 0 1988 IVF 1
GIFT — GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 0 1988 IVF 0
GIFT — GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 1 25 % twins
GIFT — — % —

1988 IVF 2 50 % twins (1 set delivered; 1 set ongoing)
GIFT 0 0 % 0

21. What are the qualifications of the director of the embryo laboratory? Ph.D. in Reproductive Physiology with specialty in embryo culture. Approved by the American Embryo Transfer Association.

22. Who supervises the laboratory director? M.D

23. Does the clinic participate in an external laboratory proficiency testing program? No
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? Yes

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? Yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? Yes

27. Does the clinic train individuals in IVF or GIFT? No
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) ______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses _______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

Major revisions in technology Undertaken in Mid 1988.

RECEIVED
1988
Ron Wyden

IVF/GIFT SURVEY

CLINIC NAME: Advanced Institute of Fertility
ADDRESS: 2000 W. Kilbourn Ave. Milwaukee WI 53233
Waukesha Memorial Hosp 705 American Ave Waukesha WI 53186

CONTACT PERSON: Cindy Gunnarson
PHONE NUMBER: (414) 937-5437 (414) 544-2722

INSTRUCTIONS: Please provide the information for 1987 and 1988 to date, or, for the newer clinics, the most recent year of operation. Additionally, please provide answers to the questions by year and, where applicable, by IVF and GIFT categories separately.

1. The following data is current through what date? 8/1988
2. Does your clinic perform IVF/GIFT treatments? yes
   (If the answer is no, there is no need to complete the remainder of the questionnaire.)
3. What type of clinic do you operate? (Place X in appropriate space)
   (a) Private X - Kilbourn Avenue
   (b) Community hospital based X - Waukesha mem. Hosp
   ~~(c)~~ University based ____
   ~~(d)~~ Other (explain) ____
4. How many Board Certified and/or Board Eligible Reproductive Endocrinologists participate in your clinic? one
5. How many Board Certified Obstetricians/Gynecologists participate in your clinic? Three
6. How many other professionals participate in your clinic?
   (a) Physicians 3
   (b) Laboratory Scientists (PhDs) One of the mDs
   (c) Nurses 4
   (d) Embryo Lab Technicians/Technologists 2½
   (e) Other Lab Technicians/Technologists 5-Endocrine Techs
   (f) Radiology (Ultrasound) Technicians 4
   (g) Psychologists/Counselors 0
   (h) Secretaries 4
   (i) Other (specify) ONE - PA.
7. How many years has your infertility clinic been in operation? Since 3/84
8. When were the clinic's first IVF/GIFT stimulation cycles?
   IVF 3/84 GIFT 1985

9. How many different patients were stimulated? our records are not organized in a fashion to reflect this data.
1987 IVF ______ 1988 IVF ______
GIFT ______ GIFT ______

10. How many stimulation cycles were performed?
1987 IVF ______ 1988 IVF ______
GIFT ______ GIFT ______

11. For those clinics offering IVF:
How many egg recovery procedures were performed?
1987 351 1988 351

How many embryo transfer cycles were performed?
1987 260 1988 287

12. How many GIFT procedures (attempted egg recoveries) were performed?
1987 29 1988 33

13. What were the number and percentage of patients on IRB approved research protocols?
1987 0 0% 1988 0 0%

14. What were the number and percentage of patients treated for:

Approximate

(a) Tubal factor:
1987 IVF ___ 62% 1988 IVF ___ 53%
GIFT ___ ___% GIFT ___ ___%

(b) Endometriosis:
1987 IVF ___ 11% 1988 IVF ___ 18%
GIFT ___ ___% GIFT ___ ___%

(c) Male infertility:
1987 IVF ___ 12% 1988 IVF ___ 18%
GIFT ___ ___% GIFT ___ ___%

(d) Unexplained infertility:
1987 IVF ___ 4% 1988 IVF ___ 0%
GIFT ___ ___% GIFT ___ ___%

(e) Other (explain): AD
1987 IVF ___ 10% 1988 IVF ___ 11%
GIFT ___ ___% GIFT ___ ___%

15. What were the number and percentage of patients in the following age groups:

(a) <31:
1987 IVF 104 33% 1988 IVF 91 31%
GIFT ___ ___% GIFT ___ ___%

(b) 31-35:
1987 IVF 138 44% 1988 IVF 55 41%
GIFT ___ ___% GIFT ___ ___%

(c) 36-40:
1987 IVF 50 16% 1988 IVF 32 24%
GIFT ___ ___% GIFT ___ ___%

(d) 41-45:
1987 IVF 7 22 % 1988 IVF 15 5 %
GIFT ___ ___ % GIFT ___ ___ %

(e) >45:
1987 IVF 1 <1 % 1988 IVF 0 0 %
GIFT ___ ___ % GIFT ___ ___ %

16. How many clinical pregnancies were produced?
1987 IVF 57 1988 IVF 54
GIFT 4 GIFT 5

17. How many women delivered live infants from IVF/GIFT?
1987 IVF 36 (1988 to date) IVF 46
GIFT 4 GIFT 4

18. How many women have continuing pregnancies from IVF/GIFT?
1987 IVF all delivered 1988 IVF 52
GIFT GIFT 0

19. How many ectopic pregnancies resulted?
1987 IVF 2 1988 IVF 2
GIFT 0 GIFT 0

20. What were the number, percentage of all births, and plurality, of multiple births?
1987 IVF 6 17 % 4 twins, 1 triplet, 1 quad
GIFT 0 ___ % ___

1988 IVF 10 28 % 6 Twin, 2 triplet
GIFT 1 25 % Twins

21. What are the qualifications of the director of the embryo laboratory? M.S. B.S. degrees Gentics / Biology

22. Who supervises the laboratory director? MD/PhD

23. Does the clinic participate in an external laboratory proficiency testing program? NO
If the answer is yes, please specify which program.

24. Is the clinic associated with an American Board of Obstetricians and Gynecologists Fellowship Program in Reproductive Endocrinology, which includes training for IVF/GIFT? NO

25. Does the clinic conform to the American Fertility Society's published minimum guidelines (Fertility and Sterility, 41:13, 1984)? yes

26. Is the clinic a member of the Society for Assisted Reproductive Technology? yes

27. Does the clinic train individuals in IVF or GIFT? NO
If the answer is yes, how many individuals in the following specialties have been trained?
    (a) Physicians ________
    (b) Laboratory scientists (PhDs) _______
    (c) Embryo laboratory technicians/technologists _____
    (d) Nurses ______
    (e) Other (explain) ________

28. Please provide any comments you may have on your clinic's patient population, treatments or success rates in the space provided below. Those comments will be published along with your responses to the above questions to more fully explain the operation of your clinic.

NO Age restriction
NO male factor restriction
NO waiting List
NO restriction on number of attempts/patient
Low rate of cancelled cycles.

O